# EXHIBIT 35

**IN THE UNITED STATES DISTRICT COURT**
**FOR THE NORTHERN DISTRICT OF OHIO**
**EASTERN DIVISION**

| | | |
|---|---|---|
| IN RE NATIONAL PRESCRIPTION OPIATE LITIGATION | : | MDL No. 2804 |
| | : | CASE NO. 17-MD-2804 (DAP) |
| | : | |
| | : | |

Expert Report of Ronald W. Buzzeo, R.Ph.

May 31, 2019

# EXHIBIT 35

**EXPERT REPORT OF RONALD W. BUZZEO**
**IN RE NATIONAL OPIATE LITIGATION**


I. Introduction ..... 1
A. Qualifications ..... 1
B. Engagement for this Litigation ..... 2
II. Assignment and Materials Considered ..... 3
III. Summary of Opinions ..... 3
IV. Methodology ..... 4
V. Regulatory Scheme and DEA Oversight ..... 4
A. Supply Chain Overview ..... 4
B. DEA Oversight: Registration ..... 6
C. DEA Oversight: Quota ..... 7
D. DEA Oversight: ARCOS ..... 9
VI. Anti-Diversion Regulations ..... 9
A. Statutory Duty: 21 U.S.C. § 823(a)(1) ..... 10
B. Regulatory Duty: 21 C.F.R. Section 1301.74(b) ..... 11
C. There is no statutory or regulatory obligation for manufacturers to know their customers' customers ..... 12
D. There is no statutory or regulatory obligation to collect, maintain, or utilize downstream transactional data, including chargeback data, for purposes of suspicious order monitoring ..... 13
VII. Mallinckrodt's Anti-Diversion Program Was Consistent with Anti-Diversion Regulations, Guidance, and Industry Standards During the Review Period ..... 15
A. 1998-2007: Excessive Purchase Reporting ..... 15
1. 1998-2007 Regulatory Landscape ..... 15
2. 1998-2007 DEA Guidance ..... 16
3. 1998-2007 Industry Standards ..... 17
4. 1998-2007 Mallinckrodt Program ..... 17
B. 2008-2009: Shift to Peculiar Order Reporting ..... 20
1. 2008-2009 Regulatory Landscape ..... 20
2. 2008-2009 DEA Guidance ..... 20
3. 2008-2009 Industry Standards ..... 21
4. 2008-2009 Mallinckrodt Program ..... 22
C. 2010-2011: Incorporation of Chargeback Data ..... 28
1. 2010-2011 Regulatory Landscape ..... 28
2. 2010-2011 DEA Guidance ..... 28
3. 2010-2011 Industry Standards ..... 29
4. 2010-2011 Mallinckrodt Program ..... 30
D. 2012 to 2018: Continuing Evolution and Enhancement ..... 34
1. 2012-2018 Regulatory Landscape ..... 34
2. 2012-2018 DEA Guidance ..... 34
3. 2012-2018 Industry Standards ..... 34
4. 2012-2018 Mallinckrodt Program ..... 35
VIII. Mallinckrodt's 2017 Settlement Does Not Establish Or Recognize Any "Know Your Customers' Customers" Requirement And Does Not Change Opinion Regarding Mallinckrodt's Compliance With The CSA ..... 36
IX. McCann and Keller Methodologies for Flagging Transactions ..... 37

# I. Introduction

## A. Qualifications

1. I graduated from St. Johns University, College of Pharmacy, and received a Bachelor of Science degree in Pharmacy in 1963.

2. Upon graduating from St. John's University, College of Pharmacy, with a Bachelor of Science degree, I practiced as a licensed pharmacist from 1963 to 1966. I was a licensed pharmacist in the states of Virginia and New York. I later retired my pharmacist licenses as I was not practicing.

3. In 1966, I began working for the New York State Department of Health, Bureau of Narcotic Control, inspecting nursing homes, pharmacies, and hospitals, and investigating forged prescriptions.

4. I entered federal service in 1969 with the Bureau of Narcotics and Dangerous Drugs ("BNDD"), the predecessor agency to the Drug Enforcement Administration ("DEA"), where I was assigned from 1969 to 1973 as a Special Agent in the New York Regional Office. I conducted criminal and regulatory investigations of dosage form and bulk manufacturers, distributors, hospitals, researchers, analytical laboratories, importers, exporters and pharmacies.

5. I attended the BNDD Training School in 1969. This consisted of a multi-month intensive training program which covered topics related to controlled substances including investigative techniques, undercover work, firearms training, and rules and regulations. While stationed in New York with the BNDD, I also attended the University of Rhode Island College of Pharmacy for one month to take a summer course on pharmaceutical manufacturing of controlled substances.

6. In 1972, I was promoted to Group Supervisor at DEA. As a Group Supervisor, I supervised both Special Agents and Diversion Investigators.

7. In 1973, I was transferred to DEA headquarters in Washington DC where I was assigned to head the newly formed Diversion Prevention Program, staffed by a specialized work force of Diversion Investigators. At this time, I changed my position from a Special Agent to a Diversion Investigator. I was assigned to head and build out the Diversion Prevention Program. In this position I guided the implementation of domestic and worldwide programs associated with preventing the diversion of legally produced controlled substances and chemicals, formulated legislation and regulations to curtail potential diversion, evaluated controlled substances for scheduling under the CSA, and established security and recordkeeping systems and audit and investigative procedures. I also represented DEA in meetings and conferences with officials from international, federal, state and local agencies, the United Nations, the pharmaceutical and chemical industry, and the health care community.

8. Starting in 1973, I taught new-hire Diversion Investigators about the controlled substances regulations at DEA.

9. During my 22-year tenure with DEA, I held various management positions prior to my appointment as Deputy Director of DEA's Office of Diversion Control in 1982, where I served until retirement from federal service in 1990.

10. In 1991, I established Buzzeo Associates, LTD which specialized in providing guidance regarding the implementing regulations of the Controlled Substance Act. I later formed PDMA, Inc. to provide consulting relating to the Prescription Drug Marketing Act of 1987 (PDMA) which was signed into law by the President on April 22, 1988 and was enacted (1) to ensure that drug products purchased by consumers are safe and effective, and (2) to avoid the unacceptable risk to American consumers from counterfeit, adulterated, misbranded, sub potent, or expired drugs. The legislation was necessary to increase safeguards in the drug distribution system to prevent the introduction and retail sale of substandard, ineffective, or counterfeit drugs.

11. Buzzeo Associates, LTD and PDMA, Inc. merged into BuzzeoPDMA, Inc. BuzzeoPDMA specialized in both PDMA and CSA regulatory issues.

12. In 2005, BuzzeoPDMA was acquired by Dendrite; in 2007 Dendrite was acquired by Cegedim; and in 2015 Cegedim was acquired by IMS Health.

13. I retired on August 1, 2016 from IMS Health after 50 years working as a pharmacist, state investigator, Special Agent, Diversion Investigator, President of a regulatory and outsource company and Chief Regulatory Officer of the BuzzeoPDMA business unit.

14. I am currently an Independent Consultant.

15. I have had numerous TV, radio and press interviews and extensive public speaking before law enforcement agencies, major pharmaceutical companies, professional associations, civic groups, and school children and their parents. I have had articles published in a number of professional publications, such as the NARC Officer, Drug Topics, U.S. Pharmacist, American Druggist, ASIS Security Management, other professional bulletins and co-authored the "Pharmacist's Controlled Substances Regulatory Guide and Compliance Manual" and the "CSA Compliance and Counseling Kit" for pharmacists.

16. I also served as President and Treasurer of the International Narcotic Enforcement Officers Association (INEOA) whose membership consisted of representatives from the law enforcement community, industry, and medical professions and represented the United States at a number of international and UN sponsored forums. I was a member of the National Advisory Committee to the Robert Wood Johnson Foundation for Pain Management and State Regulatory Policy and also served as the Chairman of the American Society for Industrial Security (ASIS) Substance Abuse Committee for six years.

17. My CV is attached as **Exhibit A**.

**B. Engagement for this Litigation**

18. For my services as an expert witness, I am billing at a rate of $450.00 per hour plus reimbursement for expenses. My compensation is not dependent on my testimony or on

the outcome of this case. All my opinions in this report are offered to a reasonable degree of professional certainty. I reserve the right to modify or supplement my opinions and this report should additional information become available.

## II. Assignment and Materials Considered

19. I have been asked by counsel for Mallinckrodt LLC and SpecGx LLC (together "Mallinckrodt") to review the expert reports produced by the Track One Plaintiffs, in particular those related to the Controlled Substances Act, its implementing regulations, and the Defendants' suspicious order monitoring programs. In particular, I have focused on the reports of Seth Whitelaw, James Rafalski, Lacey Keller, and Craig McCann (together "Plaintiffs' Experts"). I have reviewed these reports based on my years of industry experience focusing on the Controlled Substances Act and its implementing regulations and have identified flaws in the assumptions, methodologies, and incomplete facts upon which these reports are based.

20. I have also been asked by counsel for Mallinckrodt to review Mallinckrodt's suspicious order monitoring program and anti-diversion program consistent with my years of industry experience auditing manufacturers and distributors of controlled substances and evaluate to a reasonable degree of certainty the effectiveness of Mallinckrodt's programs based on the requirements of the Controlled Substances Act and its implementing regulations; evolving DEA guidance; and evolving industry standards from 1998 to 2018 (the "Review Period").

21. In preparing this report, I reviewed the Controlled Substances Act and its implementing regulations; DEA and industry guidance; Plaintiffs' Experts' reports; court filings; documents produced in this litigation; and certain depositions taken in this litigation. I have also relied on my more than fifty years of experience in the industry, including my 22 years working for DEA. A list of materials that I have considered is attached as **Exhibit B**.

## III. Summary of Opinions

22. It is my opinion that during the Review Period Mallinckrodt maintained sufficient and effective controls against diversion of controlled substances.

23. It is my opinion that during the Review Period Mallinckrodt's suspicious order monitoring system was sufficient and effective to detect and report suspicious orders to DEA.

24. It is my opinion that throughout the Review Period DEA guidance and industry standards evolved over time and Mallinckrodt enhanced and upgraded its suspicious order monitoring and anti-diversion programs to meet changing DEA guidance and industry standards.

25. It is my opinion that there is no statutory or regulatory obligation for manufacturers to monitor downstream registrants that are not their customers.

26. It is my opinion that Mallinckrodt appropriately utilized the information and data available to it in its controlled substances compliance program and its suspicious order monitoring program.

27. It is my opinion that a suspicious order monitoring system that meets the regulations and expectations of DEA must be tailored to each individual registrant's business and the one-size-fits-all approach that Plaintiffs' counsel asked Dr. McCann and Ms. Keller to apply in their expert reports in this case is incorrect and does not identify suspicious orders placed to each of the Defendants.

## IV. Methodology

28. During my fifty years of experience in the industry, I have conducted dozens of audits of compliance systems, anti-diversion efforts, and suspicious order monitoring programs for DEA registrants. I have audited and evaluated suspicious order monitoring programs and anti-diversion programs of a number of controlled substances pharmaceutical manufacturers. I have assisted numerous registrants including controlled substances manufacturers in implementing suspicious order monitoring programs and anti-diversion programs.

29. In preparing this report, I evaluated Mallinckrodt's suspicious order monitoring program and anti-diversion efforts in the same way as I have in the dozens of audits and evaluations of controlled substances registrants in my fifty years of experience. Consistent with industry standards and past practices, I reviewed: standard operating procedures; transcripts of testimony of those individuals most intimately involved in the controlled substances program, the suspicious order monitoring system and anti-diversion efforts; internal communications and documentation of Mallinckrodt's processes and procedures, Mallinckrodt's communications with federal entities including DEA; the Controlled Substances Act and implementing regulations; DEA guidance; and testimony relating to DEA's interpretation and expectations regarding the Controlled Substances Act and its implementing regulations.

## V. Regulatory Scheme and DEA Oversight

### A. Supply Chain Overview

30. Under the Controlled Substances Act ("CSA"), DEA is responsible for control and oversight of the "closed system of distribution" of controlled substances. In the 'closed system of distribution,' all handlers of controlled substances must be registered with DEA.

31. Every person or entity that manufactures, distributes, dispenses, imports, or exports any controlled substance or who proposes to engage in the manufacture, distribution, dispensing, importation or exportation of any controlled substance must obtain a registration unless exempted.[1] The key registrants in the controlled substances supply chain are importers, manufacturers, distributors, pharmacies, and physicians.

[1] 21 C.F.R. § 1301.11(a).

32. An importer must possess a registration and permit to import into the custom territory of the United States from any place outside of the United States a Schedule I or II controlled substance or any narcotic controlled substance listed in Schedule III, IV, or V.[2] The importer may distribute the controlled substance, for which the registration was issued, to another registrant.[3]

33. A manufacturer may distribute the controlled substance for which DEA has issued the registration and may conduct chemical analysis and preclinical research (including quality control analysis) with controlled substances listed in those schedules for which authorization as a manufacturer was issued by DEA.[4] A manufacturer with a DEA registration may distribute any of the controlled substances it manufactures to any entity which possesses the required registration, including, a distributor, chain pharmacy distribution center, wholesaler, or hospital.[5] Generally, manufacturers have little to no interaction with dispensers like hospitals and independent pharmacies that dispense a controlled substance, as they sell their product to distributors and wholesalers who then distribute the product to their own registrant customers.

34. A distributor purchases controlled substances from manufacturers and then sells the product to DEA registered dispensers like hospitals and independent pharmacies.[6] Distributors may also sell to other registered distributors.[7]

35. A pharmacy, pursuant to its registration, may dispense a controlled substance pursuant to a prescription for a legitimate medical requirement; return controlled substances; and dispose of controlled substances.[8]

36. To prescribe controlled substances, a physician must obtain a registration that lists the schedules for the controlled substances the physician intends to dispense or prescribe.[9] In addition, a physician must ensure that the prescription is for a legitimate medical requirement.[10] In my experience, when a physician prescribes a controlled substance, the physician will write either the brand name or the generic of the drug prescribed and if the branded product has a generic version, the dispensing pharmacist typically will substitute the generic product for the brand unless the physician has written that the dispenser is to prescribe as written. If a generic is dispensed, the pharmacist dispenses the generic product that the pharmacy happens to have on hand at that time, regardless of the manufacturer.

---

[2] 21 C.F.R. § 1312.11(a).
[3] 21 C.F.R. § 1301.13(e)(1)(viii).
[4] 21 C.F.R. § 1301.13(e)(1)(i).
[5] 21 C.F.R. § 1301.13(e)(1)(ii).
[6] 21 C.F.R. § 1301.13(e)(1)(ii).
[7] 21 C.F.R. § 1301.13(e).
[8] 21 C.F.R. § 1301.13(e)(1)(iv).
[9] 21 C.F.R. § 1306.03(a)(2).
[10] 21 C.F.R. § 1306.04(a).

37. Each level of the supply chain has different requirements for records, security, accountability, labeling, and anti-diversion efforts as outlined in the CSA and implementing regulations.

### B. DEA Oversight: Registration

38. DEA decides who may handle controlled substances. An entity must register with DEA before it may lawfully purchase, sell, and handle controlled substances.[11] No person who is not registered may engage in any activity with controlled substances.[12] When an entity's registration application is approved, DEA issues a Certificate of Registration.[13] Certificates of Registration are not indefinite; they have an expiration date and registrants must renew their registration in order to continue handling controlled substances.[14] Manufacturers must renew their registration annually.[15]

39. There are several types of DEA registrations, depending on the entities' primary activities with respect to controlled substances. These registrations include: manufacturer, distributor, reverse distributor, researcher, analytical lab, importer, exporter, pharmacy, hospitals, physicians, and narcotic treatment program.[16]

40. In order to issue a new registration, DEA must determine that such registration is consistent with the public interest in accordance with the CSA.[17] For manufacturers and distributors, DEA must determine on a yearly basis that the registration remains in the public interest.[18]

41. A registrant who engages in more than one activity must obtain a separate registration for each activity.[19] A DEA registrant is also authorized to engage in certain coincident activities without obtaining a registration to engage in such coincident activities, unless specifically exempted, if he/she complies with all requirements and duties prescribed by law for those registered to engage in such coincident activities.[20]

42. In the case of an application for registration or reregistration to manufacture in bulk a basic class of controlled substance listed in Schedule I or II, DEA will, upon the filing of an application, publish in the Federal Register a notice naming the applicant and stating that the applicant has applied to be registered as a bulk manufacturer of a basic class of narcotic or nonnarcotic controlled substance.[21] These requirements for publication do not apply to

---

[11] 21 C.F.R. § 1301.11(a).
[12] 21 C.F.R. § 1301.13(a). While there are certain statutory and regulatory exceptions to this rule, these are irrelevant to the conclusions in my report and so I do not discuss them here.
[13] 21 C.F.R. § 1301.13(a).
[14] 21 C.F.R. § 1301.13(b).
[15] 21 C.F.R. § 1301.13(e)(1)(i).
[16] 21 C.F.R. § 1301.13(e)(1)(i–x).
[17] 21 C.F.R. § 1301.13(e); 21 U.S.C. § 823.
[18] 21 C.F.R. § 1301.13(e)(1)(i–ii); 21 U.S.C. § 823.
[19] 21 C.F.R. § 1301.13(e).
[20] *Id.*
[21] 21 C.F.R. § 1301.33(a).

the manufacture of basic classes of controlled substances listed in Schedules I or II as an incident to research or chemical analysis as authorized in the regulations.[22]

43. DEA has the authority to audit registrants to ensure compliance with the CSA.[23] DEA has many tools at its disposal to take action against any registrant that may not be in compliance with the CSA or implementing regulations, including letters of admonition, licensing hearings, orders to show cause, and immediate suspension orders.[24] DEA can also seek civil or criminal penalties for violations of the CSA.[25]

### C. DEA Oversight: Quota

44. DEA decides how much of each Schedule I and II controlled substance each registrant can manufacture and/or sell. There are three types of quotas established annually by DEA to regulate the manufacture and distribution of Schedules I and II controlled substances.[26]

45. The quota system was instituted under the Narcotic Manufacturing Act of 1960 in order for the United States to be in compliance with the international Single Convention on Narcotic Drugs.[27] The purpose of quotas was to limit exclusively to medical and scientific purposes the manufacture of narcotic drugs.[28] With the passage of the CSA in 1970, the system was revised to establish quotas on a calendar year basis for all Schedule I and II controlled substances.[29] Quota is one of the tools used by DEA (along with registration, records, security provisions, reporting requirements, scheduling, and import and export controls) to establish a closed system for the legitimate distribution chain.

46. Aggregate production quota places a national limit on the amount of each controlled substance in Schedules I and II which may be produced in a given year.[30] DEA, with the advice of the Food and Drug Administration, establishes production quotas for each basic class of controlled substances in Schedules I and II to be manufactured each calendar year to provide for the estimated medical, scientific, research and industrial needs of the United States, for lawful export requirements, and for the establishment and maintenance of reserve stocks.[31]

47. Manufacturing quota is the amount of a controlled substance a company can produce in a given calendar year.[32] DEA issues individual manufacturing quotas to registered bulk manufacturers.[33] Manufacturing quotas are determined on the basis of each manufacturer's

[22] 21 C.F.R. § 1301.33(c).
[23] 21 C.F.R. § 1301.31.
[24] 21 C.F.R. § 1301.36(a)–(e).
[25] 21 U.S.C. § 843(d); 21 C.F.R. § 1316.31.
[26] 21 U.S.C. § 826(a)(1).
[27] Pub. Law 86-429 Eighty-Sixth Cong., 1960-1 C.B. 789 (I.R.S. 1960).
[28] Pub. Law 86-429 Eighty-Sixth Cong., 1960-1 C.B. 789 (I.R.S. 1960).
[29] 21 U.S.C. § 826.
[30] 21 C.F.R. § 1303.11.
[31] 21 U.S.C. § 826(a); 21 C.F.R. § 1303.11.
[32] 21 C.F.R. § 1303.21.
[33] 21 C.F.R. § 1303.22.

estimated sale of inventory and other special requirements.[34] Additional factors considered are the manufacturer's current rate of sales; the trend of the national sales rate during the preceding calendar year; the production cycle; the inventory position; as well as economic availability of raw materials, along with yield and stability problems.[35] For a given controlled substance in each calendar year, the sum of the manufacturing quotas must be equal to or less than the aggregate production quota for that substance.[36]

48. Procurement quota is issued to registered manufacturers who purchase the bulk controlled substance and formulate the substance into finished dosage forms.[37] Procurement quotas are issued annually by the "share-of-the-market theory" to the various procurement quota applicants.[38] Share-of-the market is determined by calculating the percentage of business a firm did in a particular basic class the previous year as compared to the total sales of all the firms utilizing that same basic class.[39]

49. DEA is required to set the aggregate production quota consistent with the estimated medical, scientific, research, and industrial needs of the United States.[40] In determining the amount of aggregate production needed by the United States, DEA considers such factors as: estimates from IMS Health on retail consumption based on prescriptions dispensed; data from DEA's internal ARCOS tracking system; past histories of quota granted; estimates of the projected medical, scientific, and reserve stock needs provided by FDA's controlled substances staff; manufacturers' production history and anticipated needs; data on diversion of controlled substances, such as information from case seizures and national databases of drug evidence; and any other information that DEA deems relevant.[41] As Stacy Harper-Avilla, DEA's designated witness on this topic made clear, each of these factors was considered during the Review Period.[42] Based on these considerations, DEA sets the total amount of material for each controlled substance that may be manufactured in a given year.[43] This amount is adjusted by inventory requirements of the bulk manufacturers and apportioned among them, through manufacturing quotas based upon their respective historical share of the market.[44] The sum of these manufacturing quotas does not and cannot exceed the aggregate production quota.[45]

50. A manufacturer may not manufacture and distribute beyond the manufacturing or procurement quota provided to it by DEA in a calendar year.[46] If market conditions change

[34] 21 C.F.R. § 1303.22.
[35] 21 C.F.R. § 1303.22.
[36] 21 C.F.R. § 1303.26.
[37] 21 C.F.R. § 1303.12(b).
[38] 21 C.F.R. § 1303.12(c).
[39] 21 C.F.R. § 1303.11.
[40] 21 C.F.R. § 1303.11(a).
[41] US-DEA-00015423 at 9-10.
[42] Harper-Avilla Dep. Tr. at 50:2-57:3.
[43] US-DEA-00015423 at 9-10.
[44] US-DEA-00015423 at 9-10.
[45] 21 C.F.R. § 1303.11; 21 C.F.R. § 1303.26.
[46] 21 C.F.R. § 1303.21.

and DEA does not provide additional quota before the end of the year, a manufacturer places the product on backorder until they receive new quota from DEA.

### D. DEA Oversight: ARCOS

51. DEA can see the details of every transaction of Schedule I and II controlled substances as well as narcotic controlled substances in Schedule III in DEA's Automation of Reports and Consolidated Orders System (ARCOS) database.[47] To feed the ARCOS database, DEA requires registrants to report transactions of those controlled substances.[48]

52. Acquisition/distribution transaction reports must be filed by registrants at least every quarter, or more frequently depending on the number of transactions reported by the registrant.[49] In addition to reporting acquisition/distribution transactions, each registrant who is registered to manufacture controlled substances in bulk or dosage form must report manufacturing transactions on controlled substances in Schedules I and II, and each narcotic controlled substance listed in Schedule III.[50]

53. All ARCOS reports must be filed with DEA.[51] The registrant must provide the data in a manner as to identify the particular form, strength, and trade name, if any, of the product containing the controlled substance for which the report is being made.[52] Registrants filing reports must utilize the National Drug Code Number assigned to the product under the National Drug Code System of the Food and Drug Administration.[53]

54. Thus, all transactions of the Schedule II opioids at issue in this matter are reported to DEA and reflected in the ARCOS database. Through the reporting by manufacturers and distributors of Schedule II opioid products, among other products, DEA has full visibility of opioids through the distribution chain to the pharmacy level on a nationwide basis. This allows DEA to determine orders and purchases that may warrant DEA review.

## VI. Anti-Diversion Regulations

55. The supply chain for controlled substances is regulated by DEA based on the Controlled Substances Act and its implementing regulations.[54] The anti-diversion language of the CSA has not changed since 1971, nor has the suspicious order monitoring regulation.[55]

---

[47] Wright Dep. Tr. Vol. 1 at 215:20-218:21.
[48] 21 C.F.R. § 1304.33(d)(1) (2018).
[49] 21 C.F.R. § 1304.33(b).
[50] 21 C.F.R. § 1304.33(c).
[51] 21 C.F.R. § 1304.33(a).
[52] 21 C.F.R. § 1304.33(d)(2).
[53] 21 C.F.R. § 1304.33(d)(2).
[54] 21 U.S.C. § 826; 28 C.F.R. § 0.100 (2018).
[55] 21 C.F.R. § 1301.71(b).

### A. Statutory Duty: 21 U.S.C. § 823(a)(1)

56. The CSA requires that manufacturers must maintain "effective controls against diversion of particular controlled substances into other than legitimate medical, scientific, and industrial channels" in order to obtain and keep a license to manufacturer controlled substances.[56] It further requires that:

> All applicants and registrants shall provide effective controls and procedures to guard against theft and diversion of controlled substances. In order to determine whether a registrant has provided effective controls against diversion, the Administrator shall use the security requirements set forth in Secs. 1301.72-1301.76 as standards for the physical security controls and operating procedures necessary to prevent diversion.[57]
>
> In evaluating the overall security system of a registrant or applicant, the Administrator may consider any of the following factors as he may deem relevant to the need for strict compliance with security requirements: (1) The type of activity conducted (e.g., processing of bulk chemicals, preparing dosage forms, packaging, labeling, cooperative buying, etc.); (2) The type and form of controlled substances handled (e.g., bulk liquids or dosage units, usable powders or non-usable powders); (3) The quantity of controlled substances handled; (4) The location of the premises and the relationship such location bears on security needs; (5) The type of building construction comprising the facility and the general characteristics of the building or buildings; (6) The type of vault, safe, and secure enclosures or other storage system (e.g., automatic storage and retrieval system) used; (7) The type of closures on vaults, safes, and secure enclosures; (8) The adequacy of key control systems and/or combination lock control systems; (9) The adequacy of electric detection and alarm systems, if any including use of supervised transmittal lines and standby power sources; (10) The extent of unsupervised public access to the facility, including the presence and characteristics of perimeter fencing, if any; (11) The adequacy of supervision over employees having access to manufacturing and storage areas; (12) The procedures for handling business guests, visitors, maintenance personnel, and nonemployee service personnel; (13) The availability of local police protection or of the registrant's or applicant's security personnel; (14) The adequacy of the registrant's or applicant's system for monitoring the receipt, manufacture, distribution, and disposition of controlled substances in its operations; and (15) The applicability of the security requirements contained in all Federal, State, and local laws and regulations governing the management of waste.[58]

57. Based on my experience with DEA, I understand that the CSA requires registrants to maintain effective controls against diversion while the product is under their control. Each registrant is responsible for the product until it is received by another registrant. This focus

[56] 21 U.S.C. § 823(a)(1).
[57] 21 C.F.R. § 1301.71(a).
[58] 21 C.F.R. § 1301.71(b).

of the statutory language is made clear by the security requirements laid out in 21 CFR 1301.71-1301.93. The expectation of the CSA is not that the registrant polices the entire supply chain, but rather that the registrant maintains effective controls against diversion and adequate security measures while it has control over the product.[59]

58. The CSA does not define what "effective controls" means, does not contain examples of what constitutes "effective controls" and does not provide any further guidance about what manufacturers are required to do, but it is clear on its face that the focus is on preventing diversion while product remains in the registrant's control.

59. 21 CFR 1301.74(b) is no different. It focuses on what a registrant must do in relation to its orders from its own customers while the product is still under the registrant's control.

**B. Regulatory Duty: 21 C.F.R. Section 1301.74(b)**

60. 21 CFR 1301.74(b) states: "The registrant shall design and operate a system to disclose to the registrant suspicious orders of controlled substances. The registrant shall inform the Field Division Office of the Administration in his area of suspicious orders when discovered by the registrant. Suspicious orders include orders of unusual size, orders deviating substantially from a normal pattern, and orders of unusual frequency."[60]

61. Neither the CSA nor any of the implementing regulations defines the term "unusual size." Neither the CSA nor any of the implementing regulations defines the term "normal pattern." Neither the CSA nor any of the implementing regulations defines the term "unusual frequency." I understand that several current and former DEA officials have testified in this case, and all agree that DEA has not defined any of these terms.[61]

62. Instead, DEA left it up to registrants to determine what those terms meant and to create and design their own suspicious order monitoring program accordingly. Based on my experience in DEA and in industry, I understand that DEA did not define these terms in part because it believed there was no one-size-fits-all approach to suspicious order monitoring.[62] In fact, DEA 30(b)(6) witness Thomas Prevoznik admitted that there is "no single feature that makes a suspicious order monitoring system compliant" and agreed that

[59] Rannazzisi Dep. Vol. 1, Ex. 6 at 18:20-19:8 ("People always say, well, you can't expect us to police the -- the supply chain. I said I don't expect you to police the supply chain, but I do expect you to police your own customers.").
[60] 21 C.F.R. § 1301.74(b). The regulation is clear on its face that registrants are only required to report orders that are actually suspicious.
[61] *See* Prevoznik Dep. Tr. Vol. 1 at 273:7-20 ("With respect to orders that are placed to manufacturers, what constitutes an order of unusual size in the DEA's view? A. Well, as you know from the statute regulations, the onus is on the registrant to identify it. It's not for us to identify it. It's for the registrant to identify it. So, I don't know the -- the situation. I mean it would be all hypothetical situations that I would be proposing. And I'm not sure that I can cover every single hypothetical for you."); Prevoznik Dep. Tr. Vol. 1 at 284:5-9 ("Q. But as you sit here today, you can't tell us exactly how frequent an order would have to be for it to be unusually frequent? A. No, I can't."); Ashley Dep. Tr. at 26:16-22 ("Q. Does the regulation tell -- provide guidance as to what constitutes an order of unusual size? A. No. Q. Does the regulation provide guidance as to what constitutes an order of unusual frequency? A. No.").
[62] Prevoznik Dep. Tr. Vol. 1 at 180:3-11.

"DEA leaves it up to the registrant to design a system that works with its own business model and customer base."[63]

63. For a time, DEA engaged in communications with manufacturers and distributors to discuss the suspicious order monitoring regulation and other DEA requirements. However, in my experience, DEA headquarters ceased most communications following the Rannazzisi DEA Letters of 2006 and 2007 and instead ramped up enforcement efforts.

64. The suspicious order monitoring regulation has not changed since it was implemented.[64] It is my understanding that in recent years DEA has been working on a change to the suspicious order monitoring regulation, which may further define the term "suspicious order," but there has been no notice and comment and no new regulation.[65]

### C. There is no statutory or regulatory obligation for manufacturers to know their customers' customers

65. In my experience in DEA and as an industry consultant, I have never seen or heard DEA state that there is a statutory obligation in the CSA or a regulatory obligation in the suspicious order monitoring regulation for manufacturers to know their customers' customers. Demetra Ashley of DEA testified that she was not aware of any statute or regulation that requires a manufacturer to know its customers' customers.[66]

66. In my experience in DEA and as an industry consultant, I have never seen a DEA guidance letter or other DEA public statement or suggestion reflecting an obligation for a manufacturer to know its customers' customers.[67] Based on my review of the testimony in this case, current and former DEA personnel have stated that there is no obligation for a manufacturer to monitor the activities of downstream registrants beyond its own customers. In his deposition, Joe Rannazzisi testified that he was not familiar with the phrase "know

---

[63] *Id.*

[64] Rannazzisi Dep. Tr. Vol. 1 at 253:10-23; Prevoznik's Dep. Tr. Vol. 1 at 363:16-21 ("But since 1974, DEA has not promulgated any regulation providing further guidance to registrants on the supposed obligation to monitor and report suspicious orders, correct? A. Correct.").

[65] Ashley Dep. Tr. at 57:6-19 ("Q. Let me just ask you as of this date at least, the day he wrote this e-mail, which is October of 2016, was the DEA working on possible changes to the suspicious order monitoring regulation? A. Yes. Q. When did the DEA begin working on possible changes to the suspicious order monitoring regulation? A. So I wouldn't -- I guess I'm not clear on where to begin. The discussions? Q. Yeah. A. The discussions would have been early 2016."); Ashley Dep. Tr. at 95:15-24 ( "Does this document refresh your memory as to whether at least as of this date of September 30, 2015 or a little earlier, the DEA was giving consideration to written revisions to the suspicious order monitoring regulation we've been talking about? MR. SHKOLNIK: Objection. THE WITNESS: So this document refreshes my memory that chief counsel had drafted a suspicious order document, and it was provided to me.").

[66] Ashley Dep. Tr. at 160:16-161:8 ("Q. As you sit here today, are you aware of any statute that requires a manufacturer to know its customer's customer? A. No, I am not aware of a statute that says that. Q. What about a regulation? A. No, I'm not aware of a regulation that says that.").

[67] I understand that notes from a Buzzeo conference indicate that there may have been a single discussion in 2008 about knowing ones customers' customer. As discussed in detail below, this was not an industry expectation at the time; as an industry consultant we did not consider it to be industry standard or required by the regulation. Similarly, Mallinckrodt heard a one-off comment about "know your customers' customers" during an audit in 2010, but this did not reflect the position of DEA at the time and was contradicted by others in DEA contemporaneously.

your customers' customers" while at DEA and only heard the phrase after he left DEA in 2015.[68] Similarly, Rannazzisi has made clear that he did not require registrants to monitor the entire supply chain, only their own customers.[69] Accordingly, it was not industry standard for manufacturers to know their customers' customers or monitor downstream registrants. Instead, the expectation and industry standard, consistent with the plain language of the CSA and the suspicious order monitoring regulation, was for manufacturers to monitor the orders they received from their customers (distributors, wholesalers, and distribution centers of retail pharmacy chains) and have a system in place to report suspicious orders that they received from their customers.

67. Further, the suspicious order monitoring regulation refers to "orders."[70] Mallinckrodt receives orders from its customers, which are distributors, wholesalers, and distribution centers of retail pharmacy chains. An order is a transaction between a manufacturer and its customer and DEA has never indicated that "order" refers to anything other than a transaction between the registrant and their direct customer. Every registrant has a responsibility to monitor the orders received from the customer next to it in the supply chain.[71] There is no regulatory requirement or expectation that manufacturers police the entire supply chain down to pharmacies, physicians, or patients.[72]

### D. There is no statutory or regulatory obligation to collect, maintain, or utilize downstream transactional data, including chargeback data, for purposes of suspicious order monitoring

68. Consistent with the plain language of the CSA and its implementing regulations, and in my experience in DEA and as an industry consultant, I have never seen or heard DEA state that there is a statutory or regulatory obligation for a registrant to collect, maintain, or utilize downstream transactional data, including chargeback data, for purposes of anti-diversion monitoring. In my experience in DEA and as an industry consultant, I have never seen any formal DEA guidance informing industry that registrants must collect, maintain,

---

[68] Rannazzisi Dep. Tr. Vol. 1 at 110:7-18 ("Q: Are you familiar with the phrase 'Know your customers' customer'? A: I've heard that phrase. But that phrase was used after I – I left. Q: Okay. So during your time as the head of Office of Diversion Control, 'know our customer's customer' was not a term that you were familiar with? A: No. Due diligence was the term we utilized. Due diligence on your customers. Making sure you know your customers and know what they're doing."); *see also* Prevoznik Dep. Tr. at 269:15-270:1 ("Q. Okay. So whereas a pharmacist might have to have some obligations with respect to particular prescriptions, a manufacturer does not have an obligation to review or -- or monitor particular prescriptions, correct? A. The -- the prescriptions from a pharmacy? Q. Correct. A. No they don't.").

[69] Rannazzisi Dep. Vol. 1, Ex. 6 at 18:20-19:8 ("People always say, well, you can't expect us to police the -- the supply chain. I said I don't expect you to police the supply chain, but I do expect you to police your own customers.")

[70] 21 C.F.R § 1301.74(b) (2018).

[71] *Id.*

[72] Dr. Whitelaw's claim that a manufacturer's anti-diversion program is geared towards looking down the entire supply chain is unfounded; not based on any facts, regulation, statute, or DEA guidance; and is explicitly contradicted by DEA testimony in this case. Whitelaw Rep. at 47; see *supra* n.68-71.

or utilize any downstream transactional data, including chargeback data, for purposes of anti-diversion monitoring.[73]

69. I have reviewed DEA testimony in this case and the testimony confirms that there is no regulatory requirement, obligation, or DEA expectation that manufacturers collect, maintain, or utilize chargeback data for anti-diversion monitoring. By way of example, when Mr. Wright was asked in his deposition what role chargebacks play in suspicious order monitoring, he responded "none."[74] Similarly, DEA's 30(b)(6) witness Mr. Prevoznik testified that DEA has never issued guidance to manufacturers informing them that they should review chargeback data.[75]

70. In my experience in DEA and as an industry consultant, it is not industry standard for manufacturers to collect, maintain, or utilize downstream transactional data, including chargeback data, for suspicious order monitoring and anti-diversion purposes.

71. While I was aware of chargeback data during my time as an industry consultant, it was only discussed in the context of financial arrangements between registrants. Chargebacks are a financial reconciliation method between manufacturers and their customers that take place in connection with some but not all of the customers' downstream sales.[76]

72. In more recent years, since approximately 2012, although not required by the CSA or its implementing regulations, some registrants have explored the question of how they might use alternative data sources, like downstream transactional data, to address specific instances of potential downstream diversion that they become aware of. However, based on my experience, chargebacks were never used, discussed or thought of in the industry as something to be used for suspicious order monitoring. Because chargeback data is backward looking and does not reflect "orders" placed with the manufacturer registrant, this financial data was not considered a resource or tool for the purpose of suspicious order monitoring. As discussed throughout this report, in my years of industry experience I have never been aware of any obligation requiring manufacturers to monitor chargebacks and report them as if they were orders through their suspicious order monitoring programs.

73. In addition, I am aware that prescription data is used by manufacturers for commercial purposes and by DEA for making quota determinations of controlled substances.[77] Prescription data is not order data and provides limited information about a manufacturers' product. In my experience in DEA and as an industry consultant, it was not industry

---

[73] In fact, the first time I ever heard a claim of a requirement that manufacturers must utilize downstream transactional data was in reading Plaintiffs' expert reports in this case. To the extent that Mr. Rafalski claims that any such requirement existed, this is an obligation created out of thin air. Rafalski Rep. at 145.

[74] Wright Dep. Tr. Vol. 1 at 220:22-221:3 ("[I]n your understanding, what role, if any, do charge-backs play in Suspicious Order Monitoring? A. None. Q. Okay. A. None.").

[75] Prevoznik's Dep. Tr. Vol. 1 at 347:1-5 ("[H]ad the DEA ever issued any industrywide guidance indicating that manufacturers should review chargeback data? A. Not to my knowledge."). *See also* Rannazzisi Dep. Tr. Vol. 1 at 120:6-21 (testifying that DEA has never issued "any kind of a document regarding chargebacks").

[76] *See* Buthusiem Rep. at 3-6.

[77] US-DEA-00015423 at 10, February 2015: GAO-15-202, DRUG SHORTAGES: Better Management of the Quota Process for Controlled Substances Needed.

standard for manufacturers to collect, maintain, or use prescription data for the purpose of suspicious order monitoring. Furthermore, prescriptions are not "orders" and as such, there is no obligation that manufacturers monitor prescriptions and report them as if they were orders through their suspicious order monitoring programs.

## VII. Mallinckrodt's Anti-Diversion Program Was Consistent with Anti-Diversion Regulations, Guidance, and Industry Standards During the Review Period

74. Mallinckrodt was founded in 1867 in St. Louis, Missouri to supply local pharmacists with materials and chemicals. When founded, Mallinckrodt was the only chemical supply company west of Philadelphia.[78] Mallinckrodt began producing morphine and codeine in 1898. In the twentieth century, Mallinckrodt continued to advance the production of chemicals and pharmaceutical ingredients, improving the stability and safety of numerous medications. Mallinckrodt has manufactured controlled substances, in particular active pharmaceutical ingredients, since before DEA was formed in 1971.[79] In that time, Mallinckrodt has worked in partnership with DEA to ensure that the legitimate needs of patients were met while taking steps to address the potential diversion of its products. In 2000, Mallinckrodt was acquired by Tyco International's healthcare division, which became Covidien in 2007. Mallinckrodt Pharmaceuticals later split from Covidien in 2013 to become an independent public company focusing on specialty pharmaceutical products and diagnostic imaging agents.[80]

75. While the CSA and suspicious order monitoring regulation have not changed since the 1970s, and DEA guidance has been limited, industry standards and compliance practices have evolved over time. In my experience as an industry consultant, much of this evolution is related to advancements in technology. The tools, technology, and information available in 1995, or even in 2005, are very different from tools, technology, and information available today. In my opinion, based on my experience in DEA and as an industry consultant, Mallinckrodt's anti-diversion program was consistent with the Controlled Substances Act, DEA regulations, and industry standards at all times during the Review Period, 1998 through 2018. In addition, Mallinckrodt's chargeback review and monitoring system developed in 2010 and 2011 goes above and beyond both regulatory requirements and industry standards.

### A. 1998-2007: Excessive Purchase Reporting

#### 1. 1998-2007 Regulatory Landscape

76. Based on my extensive experience in DEA and in industry, from the passage of the CSA in 1971 to late 2006, DEA worked with the industry to make sure that registrants were implementing and following registration, records, quota, ARCOS, and security requirements in the CSA. DEA's priority during this time was to investigate in-transit losses and thefts and to investigate pharmacy registrants. Prior to 2006, it is my experience that DEA focused on and devoted resources to practitioner and pharmacy-level

[78] Mallinckrodt Pharmaceuticals, *Our Story*, http://www.mallinckrodt.com/about/our-story/.
[79] *Id.*
[80] *Id.*

investigations and enforcing the security requirements of the CSA and the implementing regulations.

77. During this time, DEA expectation was that a manufacturer would report to DEA excessive purchases by its customers. As Mr. Wright confirmed in his deposition testimony, the excessive purchase reporting system was the accepted practice by DEA for many years prior to 2008.[81]

**2. 1998-2007 DEA Guidance**

78. During this time, the only limited guidance for manufacturers regarding suspicious order monitoring was in an appendix to DEA's Chemical Handler's Manual, which recommended a voluntary computer algorithm to analyze orders submitted to a registrant to flag purchases that exceeded the algorithm.[82]

79. DEA did not provide any guidance other than the Chemical Handlers Manual until it began a distributor briefing initiative concerning internet pharmacies in 2005. As Mr. Prevoznik testified, DEA had determined by 2005 that with the rise of the internet, diversion was becoming more of a national issue.[83] Therefore, DEA decided to sit down with distributors and provide them data about internet pharmacies. There was no such manufacturer initiative.[84]

80. In 2006, Joe Rannazzisi at DEA sent a letter to every commercial entity in the United States registered with DEA to distribute controlled substances with guidance on how to monitor

---

[81] Wright Dep. Tr. Vol. 1 at 72:12-16 ("Q. Now, the Excessive Purchase System had been blessed by various DEA offices; is that right? MR. BENNET: Objection. Form. THE WITNESS: Yes, ma'am."); Wright Dep. Tr. Vol. 1 at 74:10-75:9 (BY MS. MAINIGI: Q. And it's fair to say that the Excessive Purchase Reports were the accepted practice by DEA for many years; is that right? MR. BENNETT: Objection. Form. Go ahead. THE WITNESS: As far as my experience of dealing with them from when I cam on, yes, ma'am."); Prevoznik Dep. Tr. at 136:17-24 ("Q. Prior to December 27th, 2007, the date of this Rannazzisi letter, had the agency issued any written guidance to the industry stating that excessive purchase reports did not comply with the requirements the industry had under 21 C.F.R. Section 1301.74? A. I'm not aware.").

[82] Whitelaw Deposition Exhibit 13, Chemical Handler's Manual A Guide to Chemical Control Regulations (2004) at 41 ("This voluntary formula is for use by distributors to wholesale and retail levels. The formula calculates the quantity which, if exceeded in one month, constitutes an order which may be considered excessive or suspicious and therefore require reporting to DEA.").

[83] Prevoznik Dep. Tr. Vol. 1 at 298:2-20 ("What, in DEA's view, is the distributor initiative? A. Back in 2005 when we started, that was when we were addressing the internet. So it went from the regional local diversion issues to a more national -- not a more -- I mean it went national. So the distributor initiative was to be able to sit down with the distributors and go over their own data with them to discuss, A, their requirements; B, their duties; and the data that showed abnormalities so that they would have a better understanding of what was going on with the internet. Q. Was there any manufacturer initiative around the same time? A. No.").

[84] Wright Dep. Tr. Vol. 1 at 191:22-192:6 ("Q. Was there any separate manufacturer initiative that you or others undertook while at DEA? A. No. Q. During the time period that you were involved in the distributor initiatives, are you aware of any guidance the DEA provided to manufacturer registrants regarding Suspicious Order Monitoring? A. Specifically, no."); Wright Dep. Tr. Vol. 1 at 193:5-10 ("Q. Okay. As you sit here today, can you remember any guidance whatsoever that the DEA provided to manufacturer registrants regarding their obligations under the Suspicious Order Monitoring regulation? A. No.").

orders received from pharmacies.[85] The letter focused on distributors' obligations with respect to their sales to pharmacy customers.[86] It outlined "red flags" that distributors should look for when monitoring orders from pharmacies.[87] This letter made no mention of obligations specific to a manufacturer and did not reference red flags that manufacturers should look for when monitoring orders received from distributors.

### 3. 1998-2007 Industry Standards

81. As a consultant during this time, 1998-2007, I understood industry practice to be periodic reporting of excessive purchases to DEA. It is my experience in the industry that, 1998-2007, DEA headquarters and field offices expected and accepted from manufacturers excessive purchase reports, and approved excessive purchase report programs.[88] Excessive purchase reports were documentation of orders that hit on a particular algorithm that were then provided to DEA on a monthly or quarterly basis based on instructions of the local DEA office that had authority over the registrant. While all purchases on the excessive purchase reports were not necessarily indicative of diversion, Mallinckrodt reported all excessive purchases and DEA accepted these reports.

82. The goal of reporting excessive purchases was to provide DEA with information that the agency could use to determine whether to investigate certain registrants. The industry standard at the time was to provide this information to DEA and then it was DEA, not the manufacturer, who was responsible for undertaking any investigation of purchases reflected on excessive purchase reports. In my experience, the only other DEA expectation for manufacturers at this time was that they verify that each customer had a current DEA registration and that therefore DEA had determined that the customer had met the security requirements of the CSA.

83. During this time, 1998-2007, DEA also never suggested that manufacturers had any responsibilities with respect to knowing downstream registrants. DEA regulations do not require that a manufacturer review a pharmacy's registration before selling to a distributor and do not require that manufacturers examine individual patient prescriptions; there was no suggestion during this time that manufacturers should do so.

### 4. 1998-2007 Mallinckrodt Program

84. From 1998-2007, Mallinckrodt's anti-diversion program had several components that were consistent with DEA expectations and industry practice at the time. First, Mallinckrodt had an algorithm in place based on the algorithm guidance in the Chemical Handler's Manual that monitored and flagged orders.[89] The algorithm measured each customer against its

[85] US-DEA-00001767.
[86] *Id.*
[87] *Id.*
[88] Wright Dep. Tr. at 72:12-16 ("Q. Now, the Excessive Purchase System had been blessed by various DEA offices; is that right? MR. BENNET: Objection. Form. THE WITNESS: Yes, ma'am.").
[89] Harper Dep. Tr. at 58:8-61:12 (testifying that Mallinckrodt has always had a suspicious order monitoring program in place as far back as she can recall), 189:18-190:7; Spaulding Dep. Tr. at 91:16-92:13 (testifying that there has always been an algorithm in place at Hobart back to at least 2001); MNK-T1_0000289355.

previous order history and order pattern.[90] Mallinckrodt reported the orders that were flagged, sending the bulk business reports on a monthly basis to the DEA St. Louis Field Office, per their request, and sending the dosage business reports on a quarterly basis to the DEA Albany Field Office, per their request.[91] Consistent with industry standard at the time, it was Mallinckrodt's understanding and expectation that DEA used these reports to make investigatory and enforcement decisions.

85. In addition to the algorithm that generated excessive purchase reports, Mallinckrodt took additional steps to monitor incoming orders. For example, Mallinckrodt's customer service representatives reviewed orders as they were received.[92] Customer service representatives were familiar with customer and order patterns and would escalate anything that appeared to be of unusual size, frequency or pattern to the customer service manager and then to the Controlled Substances Compliance group.[93] The customer service representatives were trained on what to look for in incoming orders and how to clear Form 222s.[94] In addition, National Account Managers (NAMs) would meet with customers on a regular basis. NAMs were the "eyes and ears" of the suspicious order monitoring program and looked for red flags indicative of diversion.[95] NAMs were trained by the Controlled Substances group to bring any questions or concerns to the compliance department's attention. While NAMs served as the "boots on the ground," all decisions relating to whether an order would ship

[90] Harper Dep. Tr. at 83:24-84:20.
[91] Harper Dep. Tr. at 232:20-234:3; MNK-T1_0006805909.
[92] Gillies 30(b)(6) Dep. Tr. at 90:5-14 ("Q. And separate and apart from the algorithm, do you know whether or not Mallinckrodt utilized any other elements to identify a suspicious order at that time? . . . A. The -- every order was being reviewed by a customer service rep. So in addition to the algorithms, every order was reviewed by customer service."); Harper Dep. Tr. at 59:1-60:12 ("Q. Okay. And what did that system -- what was your understanding of what that system consisted of? A. There was a algorithm in -- programmed by IT into our order entry system that would flag orders for further review. Q. Okay. Other than that algorithm, were there any other elements of that system? … A. We have customer service representatives who are veteran in the business, and they were in general familiar with customers' order patterns, and so they had responsibility, if they saw anything that appeared to be unusual to them, to escalate to their manager. We took precautions to make certain that every single order we shipped was to a valid DEA registration, every order for Schedule II drugs was -- that we received form that was filled out correctly, and that the order -- the address on the forms coincided exactly with the ship to address in our company's order management system.); Stewart Dep. Tr. at 148:22-149:17 ("A. My opinion would be that [the Customer Service Reps] evaluated every order that they entered for anomalies, and then if they felt that something was out of sort or character, they'd bring it to my attention. Q. Okay. So they evaluated -- when you say "they evaluated every order," is that independent of whatever algorithms were put in place by the team? A. Yes. Q. And what were the criteria that they used to conduct that evaluation, independent of algorithms? A. Our customer base was -- our relationships had been very long-standing, and the customer services reps were kind of intimate with the customers. They knew exactly what they ordered and what typical quantities were and frequency. So if something seemed out of the ordinary, they would bring it up.").
[93] Rausch Dep. Tr. at 46:20-47:10.
[94] Stewart Dep. Tr. at 48:11-49:15, 148:22-149:17.
[95] Harper Dep. Tr. at 59:1-19 ("Q. Okay. And what did that system -- what was your understanding of what that system consisted of? A. There was a algorithm in -- programmed by IT into our order entry system that would flag orders for further review. Q. Okay. Other than that algorithm, were there any other elements of that system? … A. So we had commercial representative -- national account managers that were our eyes and ears and boots on the ground at the customer accounts. We trained them to be vigilant for any potential sign -- red flags that could be indicative of diversion as they visited customers.").

were made by the Controlled Substances Compliance group, not the National Account Managers.[96] These additional checks continue to this day.

86. Mallinckrodt also reviewed all new customers to check that they had a valid license.[97] As discussed above, DEA was required to determine that each registration was in the public interest and determine on a yearly basis that the registration remained in the public interest.[98] Mallinckrodt also pulled Dun and Bradstreet credit reports as part of their diligence on new customers.[99]

87. Based on my review of documents and testimony in this case, I have been unable to locate explicit standard operating procedures regarding the anti-diversion and suspicious order monitoring systems that were in place at Mallinckrodt during the 1998-2007 time period. However, given the consistency of the deposition testimony of the key individuals involved with Mallinckrodt's anti-diversion program during this time, and my experience with typical document retention policies, I believe that the suspicious order monitoring and anti-diversion practices discussed above were followed by Mallinckrodt 1998-2007.[100]

88. It is my opinion that 1998-2007, Mallinckrodt maintained sufficient and effective controls against diversion of controlled substances.

89. It is my opinion that 1998-2007, Mallinckrodt's suspicious order monitoring system was sufficient and effective to detect and report suspicious orders to DEA.[101]

90. It is my opinion that 1998-2007 Mallinckrodt appropriately utilized the information and data available to it in its controlled substances compliance program and its suspicious order monitoring program.

---

[96] Harper Dep. Tr. at 292:5-17 ("Q. Okay. So is it the case that for some orders, national account managers played an integral role in determining whether or not a peculiar order was ultimately determined to be suspicious? A. They assisted in the review, and the ultimate decision about whether the order was suspicious or not rests -- always did rest with the controlled substances compliance group.").

[97] Harper Dep. Tr. at 281:17-282:8.

[98] 21 C.F.R. § 1301.13(b).

[99] Harper Dep. Tr. at 281:17-282:8.

[100] There is no statutory or regulatory requirement that a company have written SOPs related to suspicious order monitoring. Prevoznik Dep. Tr. Vol. 1 at 358:21-59:1.

[101] To the extent Mr. Rafalski criticizes Mallinckrodt for the number of suspicious orders reported, this shows a fundamental misunderstanding of the industry and the suspicious order monitoring regulation. Rafalski Rep. at 166. In my experience, registrants may have perfect suspicious order monitoring programs that do not report any orders because none of the orders is suspicious. In fact, it is not surprising that Mallinckrodt reported a relatively small number of suspicious orders given its customer base.

### B. 2008-2009: Shift to Peculiar Order Reporting

#### 1. 2008-2009 Regulatory Landscape

91. Although DEA wrote letters to the industry in 2006 and 2007, there was no change to the CSA's anti-diversion requirements or suspicious order monitoring regulation.[102] Accordingly, consistent with prior years, neither the CSA nor the suspicious order monitoring regulation suggested that manufacturers needed to take any action to police the supply chain beyond the orders from their customers.

#### 2. 2008-2009 DEA Guidance

92. In late 2007, all registrants received a letter from Joe Rannazzisi at DEA that reflected a significant change in DEA's guidance with respect to suspicious order monitoring.[103] The 2007 DEA Letter explicitly stated that a registrant could no longer rely on past DEA statements regarding its suspicious order monitoring program.[104] DEA stated that it would no longer accept excessive purchase reports that it had expected and accepted previously. The 2007 DEA Letter undermined everything the industry had understood at all times prior to 2008. DEA stated explicitly that it would refuse to provide guidance on suspicious order monitoring programs going forward.

93. First, the 2007 DEA Letter suggested that the previously-recommended algorithm from the Chemical Handlers Manual and industry was insufficient. The Agency warned that "DEA does not approve or otherwise endorse any specific system for reporting suspicious orders. Past communications . . . that could be construed as approval of a particular system for reporting suspicious orders, should no longer be taken to mean that DEA approves a specific system."[105] In my experience, this was a significant change for the industry, required the industry to change how it implemented the suspicious order monitoring regulation, and was not based on any change to the CSA or suspicious order monitoring regulation but a new interpretation and attempts at enforcement of the same unchanged regulation.

94. Second, the 2007 DEA Letter articulated brand new guidance from DEA that: "[r]egistrants must conduct an independent analysis of suspicious orders prior to completing a sale."[106] Prior to this time, the Agency, through both headquarters and its field offices, had consistently accepted and signed off on programs in which registrants reported excessive

---

[102] Rannazzisi Dep. Tr. Vol. 1 at 253:10-23; Prevoznik Dep. Tr. Vol. 1 at 363:16-21 ("But since 1974, DEA has not promulgated any regulation providing further guidance to registrants on the supposed obligation to monitor and report suspicious orders, correct? A. Correct.").
[103] US-DEA-00005941.
[104] *Id.*
[105] *Id.*
[106] *Id.*

purchases, rather than halting orders and independently investigating the orders before shipping.[107]

95. DEA has acknowledged that the 2007 DEA Letter was a major change for industry. Kyle Wright of DEA's Office of Diversion Control confirmed in sworn testimony in a 2011 Eastern District of Michigan case that the new investigate and halt-shipment requirements were a "significant change" to registrants' obligations.[108] Mr. Wright also testified that, until the change in policy, "DEA was aware that it was standard practice in the industry to file suspicious order reports while continuing to ship products, and that practice had been approved by the DEA."[109] I understand that Mr. Wright confirmed this belief in his more recent testimony in this case.[110] Based on my experience in the industry, I agree with Mr. Wright's testimony that the 2007 DEA Letter signified a major change for the industry with little guidance on how to implement this major change in policy. Based on my experience, it is my opinion that DEA shifted responsibility for identifying potential investigative targets from the agency to industry without providing sufficient guidance to industry.[111]

96. The 2007 DEA Letter does not mention the concept of knowing your customers' customers and does not suggest collecting or utilizing downstream transactional data for suspicious order monitoring.[112] Based on my experience with DEA and industry consulting, there is nothing I reviewed in the letter that suggests that a manufacturer has an obligation to know their customers' customers or suggests that a manufacturer must collect or utilize downstream transactional data for suspicious order monitoring.

### 3. 2008-2009 Industry Standards

97. During this time, manufacturers worked to implement the brand new DEA guidance in the 2007 DEA Letter. After sending the letter, DEA did not provide any further guidance to manufacturers.[113] My understanding is that members of the industry, including Mallinckrodt, requested additional guidance and DEA did not respond.[114] DEA also

---

[107] Bench Trial Transcript at 382:24-383:18, *United States v. Four Hundred Sixty Three Thousand Four Hundred Ninety Seven Dollars and Seventy Two Cents ($463,497.72), et al.*, No. 08-11564 (E.D. Mich. Aug. 12, 2011).
[108] *Id.*
[109] *Id.*
[110] Wright Dep. Tr. Vol. 1 at 108:16-21 ("Q. Mr. Wright, the Suspicious Order System represented a significant change in DEA policy guidance and interpretation regarding Suspicious Order Monitoring, correct? MR. BENNETT: Objection. Form. THE WITNESS: I agree with the significant change.").
[111] I understand that DEA refused to provide the Diversion Investigator's Manual to industry during this time.
[112] US-DEA-00005941.
[113] Rannazzisi Dep. Tr. Vol. 1 at 277:24-278:10, 282:4-17, 334:5-13, 338:4-12; 340:14-23; Prevoznik Dep. Tr. Vol. 1 at 178:19-179:3 ("Q. So essentially there was no industrywide guidance that was provided in 2008 or forward as to how to design or implement suspicious order monitoring systems, true? . . . THE WITNESS: Nationwide, correct."); Prevoznik Dep. Tr. Vol. 1 at 285:16-21 ("Q. And aside from those 2006 and 2007 letters from Joe Rannazzisi, was there any other written guidance provided to manufacturers regarding how to identify a suspicious order? A. No."); Prevoznik Dep. Tr. Vol 1 at 305:17-22 ("Q. Since 2007 and the letter from Joe Rannazzisi, has the DEA provided manufacturers with any further written guidance regarding the obligation to monitor suspicious orders? A. No.").
[114] Wright Dep. Tr. Vol. 1 at 130:22-132:18 ("Q. But there were a lot of companies out there that were trying to figure out, get any advice in terms of figuring out how to comply with the changes, correct? . . . THE WITNESS: Yes,

decreased the number of industry conferences during this time period, effectively decreasing communications with industry.[115]

98. The 2007 DEA Letter did not provide guidance to manufacturers on what the order investigation process should look like. While the letter stated that registrants should investigate before shipping, there was no guidance about the point in time at which registrants must report. It was unclear whether registrants should report before the investigation (*i.e.*, report potentially suspicious orders that were subsequently investigated by the registrant and, if cleared, were shipped) or report after the investigation (*i.e.*, report only those orders that were confirmed suspicious after investigation and were not shipped).[116] The 2007 DEA Letter also contained no detail about how to conduct due diligence on orders and the industry had no guidance about what type of diligence DEA expected.[117]

99. Based on my experience, during the 2008-2009 time frame there was no discussion in industry that manufacturers must know their customers' customers because DEA had never mentioned an obligation or suggested that manufacturers know their customers' customers. Similarly, it was not industry practice for manufacturers to collect, maintain, or utilize any downstream transactional data for anti-diversion purposes because DEA had never mentioned the possibility of using downstream transactional data for these purposes. In my experience, the industry correctly viewed downstream transactional data as after-the-fact-data used for financial reconciliation.

#### 4. 2008-2009 Mallinckrodt Program

100. After receipt of the December 2007 DEA Letter announcing the significant change in policy, Mallinckrodt took immediate steps to enhance its program consistent with DEA's changing guidance.[118] Mallinckrodt promptly created a multidisciplinary Suspicious Order Monitoring Team ("SOM Team") to work to update its suspicious order monitoring program.[119] Mallinckrodt's SOM Team was led by members of the security, compliance, and legal departments, and also included customer service, operations, logistics, and

---

ma'am. . . . The industry was looking for a hard, fast system. DEA wasn't blessing anything."); Wright Dep. Tr. Vol. 1 at 117:13-119:3; Wright Dep. Tr. Vol. 1 at 136:8-137:7.

[115] Prevoznik's Dep. Tr. Vol. 1 at 200:24-201:15 ("Q. Sorry. This morning you told me that for the 2010-2013 time period, because of litigation and other things, there were not necessarily briefings or distributor conferences held in that time period correct? A. There were -- we had stopped with the distributor initiative and we had stopped with the conferences with the wholesalers, yes. Q. In 2010 to 2013? A. Right. Q. And you told me the main reason was because of litigation and investigations, right? A. Correct.").

[116] *See* US-DEA-00005941. Mr. Rafalski agrees that this particular issue remains unresolved by DEA to this day. Rafalski Rep. at 13.

[117] US-DEA-00005941.

[118] Rausch Dep. Tr. at 98:8-19 ("And we were instructed -- Karen Harper and Michael Pheney and some other folks put together a team of people to come up with a more robust suspicious order monitoring program, which included myself, Cathy. Karen Harper oversaw it, but she didn't come to all the meetings. We had a few IT people that was involved, to come up with a more robust ordering -- suspicious order monitoring program that would identify orders as being peculiar as the orders came through.").

[119] MNK-T1_0000274080.

commercial personnel.[120] Based on my experience, it is rational for a company to include all stakeholders in such efforts and, based on the documents I reviewed, I understand that decision-making power was retained by the compliance and legal groups.[121] Contrary to Dr. Whitelaw's statements, in my experience, it is good practice to have all stakeholders involved in an anti-diversion program to make sure the entire company is aware of expectations and the decision-making process.

101. In early 2008, Mallinckrodt received and complied with a request from the DEA St. Louis Field Office that it should stop sending excessive purchase reports.[122] During the months when Mallinckrodt had ceased sending excessive purchase reports and was working to refine the suspicious order monitoring program and algorithm, Mallinckrodt maintained its prior suspicious order monitoring and anti-diversion efforts, including (1) monitoring incoming orders; (2) understanding existing customers; (3) reviewing new customers; and (4) flagging orders as potentially suspicious and reporting to DEA.[123]

102. Starting in 2008 and continuing into 2009, Mallinckrodt engaged in a multi-year effort to enhance and improve its suspicious order monitoring program. This effort is consistent with what I would expect from an organization trying to act on new and different agency guidance in a responsible way. In order to better understand the brand new guidance in the 2007 DEA Letter, Mallinckrodt reached out to industry consultants the Drug and Chemical Advisory Group and studied industry guidelines developed by HDMA.[124] Both Mr. Rafalski and Dr. Whitelaw criticize Mallinckrodt for continuously updating its suspicious order monitoring standard operating procedures during this time period.[125] This criticism is unfounded, as I would expect a company to revise and enhance its SOPs as it evolves its program based on changing regulatory guidance. Based on my experience in the industry, this is what I would expect to see from a company trying to enhance a compliance program based on limited regulatory guidance.

103. To enhance its program consistent with the new DEA guidance, Mallinckrodt first revised its suspicious order monitoring algorithm to generate a daily Peculiar Order Report of flagged orders that raised a question as to their size, frequency, or pattern.[126] Mallinckrodt

---

[120] Harper Dep. Tr. at 68:2-69:25, 103:12-16 (SOM Team was led by members of the security, compliance, and legal, and also included customer service, operations and logistics, and commercial personnel, but does not currently include commercial or customer service).

[121] Harper Dep. Tr. at 292:12-17 ("the ultimate decision about whether an order was suspicious or not rests – always did rest with the controlled substances compliance group.").

[122] MNK-T1_0000264144; Harper Dep. Tr. at 260:3-21; Spaulding Dep. Tr. at 187:13-18 ("We stopped this because this was basically the excessive order report, and the letter came out that said they didn't want the excessive order report, so that's why we discontinued sending them to DEA. And then we would have only reported suspicious orders.").

[123] MNK-T1_0000259220 (reporting American Pharmacy Services order to DEA); MNK-T1_0000259237 (3/20/2009 Emails between P. Kliessle and B. Ratliff about potential new customer, Southern California Compounding Pharmacy. DEA approves new customer).

[124] Harper Dep. Tr. at 105:4-20; MNK-T1_0000477900.

[125] Rafalski Rep. at 162; Whitelaw Rep. at 218-220.

[126] Harper Dep. Tr. at 203:23-204:24; MNK-T1_0004604299; MNK-T1_0004154297. I understand that it took over a year for the Peculiar Order Report system to get up and running as Mallinckrodt revised and refined the policies and

reviewed and investigated the orders and determined whether they should be shipped or not shipped and reported to DEA.[127]

104. The customer service managers took a multi-step approach when conducting diligence on orders flagged on the Peculiar Order Reports.[128] First, they solicited information from Customer Service Representatives. They then reached out to Product Managers for more information about the particular product at issue in the order and the market for that product (for example, a product manager would be able to inform the customer service manager that a product was backordered). They also reached out to National Account Managers for additional information and to request further information from the customer. National Account Managers visited customers regularly and therefore had the best and most up-to-date information about any given customer and their ordering patterns.[129] The customer service representatives then took all of the collected information and made a determination as to whether the order was suspicious and should be reported. Over time, Mallinckrodt enhanced the order investigation process and developed more formal due diligence policies. While NAMs were consulted regarding specific potentially suspicious orders, the controlled substances compliance group had the final say on whether or not to

---

the algorithm. There were a number of draft policies circulated and the algorithm multiplier changed from [redacted] because the [redacted] multiplier was unworkably over-inclusive. In my experience, this is not unusual.

[127] Over time, the group responsible for monitoring shifted from customer service managers trained by the controlled substances compliance group, to trade compliance and then to controlled substances compliance personnel. While it was not improper for a customer service manager to perform the monitoring function, Mallinckrodt determined that it would be better for monitoring to be conducted in compliance.

[128] Rausch Dep. Tr. at 71:10-72:12:

> If an order was flagged as being peculiar, it was during my time, my job or responsibility to talk to marketing or our customer service reps, who would be the first people that I would talk to because they were in tuned to our customers and what their order needs were, and they would know if there was anything unusual as far as a distributor picking up a new customer that they hadn't had before that they would now need increased material to supply. And if our CSR did not have a -- an answer to why the customer was ordering more, I would go to the product manager, or business manager, whatever they were being called at the time, who had that particular product that the order was for, and I would ask them if they knew why all of a sudden we were having a peculiar order from that customer. And a peculiar order, again, would be unusual quantity from what they have bought in the past over a period of time based upon the log rhythms {sic} we set in place in our computer system. If they didn't know, my next step would be going to the salesperson and asking them.

[129] I have reviewed examples of such due diligence. I would note that due diligence is different for every order and every customer, and it is not surprising to me that ordering patterns of wholesale and distributor customers changed frequently. For example, a manufacturer exiting the market or a distributor obtaining a new customer could significantly change customer order patterns. MNK-T1_0007105639 (Carla Johnson in Logistics Planning emails Kate Muhlenkamp and Vince Kaiman about increased orders as a result of Actavis supply issues, requesting insight for the increases "[b]ecause this is a substantial increase, and we'll likely need to explain the cause.").

ship an order.[130] Generally, orders were held and not shipped during the investigation process, and Mallinckrodt never shipped a suspicious order.[131]

105. Second, to further enhance its program consistent with the new DEA guidance, Mallinckrodt revised its customer diligence processes in order to better "know its customers." This included new customer screening procedures and development of customer questionnaires[132] and checklists for existing customers, as well as an automatic "do not ship" list for customers that Mallinckrodt determined that it should not sell to.[133] It also included more training and involvement of the National Account Managers, who served as the "boots on the ground" gathering information about customers and reporting back to the Controlled Substances Compliance group.[134] Based on my review of documents and procedures, Mallinckrodt's effort to know its customers crossed departments but decision-making power was retained by the Controlled Substances Compliance group with input from the legal department.[135] Based on my experience, it is rational and appropriate for a company to include a broad group in such diligence efforts while, as here, decision-making power was retained by compliance and legal.

106. As Mallinckrodt continued to work to enhance its program based on the limited and changing DEA guidance, it also took affirmative steps when it received information suggesting the possibility of downstream diversion of its product. By way of example, on June 7, 2009, Mallinckrodt received an email from a Tennessee Police Officer alerting the Company that he was conducting an investigation into potential diversion of

[130] Harper Dep. Tr. at 292:12-17 ("the ultimate decision about whether an order was suspicious or not rests – always did rest with the controlled substances compliance group."); Stewart Dep. Tr. at 102:5-24 ("A. As the process -- as the report evolved, then we -- the intent of the report was if we could not justify or explain why we had an anomaly with the order, then we actually -- we reported it to Karen's group, and then Karen would investigate further and, if necessary, report that to DEA."); Stewart Dep. Tr. at 114:23-115:15 ("Q. So when you received a peculiar order report that identified one or more peculiar orders, what steps did you take with respect to that order? A. I investigated in the sense that who was the customer, what were the circumstances, if I knew of them. We had instances in snowstorms where trucks got stuck for days at a time on a highway. And so if I knew of a circumstance that justified the reason for the additional order, or the peculiar order, then I'd discuss it with Karen and we would release the order. If not, we kind of kicked it up the chain and said, "I can't figure out why they're ordering this," and then Karen would maybe get with marketing or whatever to resolve the problem.").

[131] I understand that for a short time, peculiar orders may have been shipped before the investigation was complete although Mallinckrodt always completed the investigations. However, none of the shipped peculiar orders were found to be suspicious, and Mallinckrodt never shipped a suspicious order. MNK-T1_0000279153; Harper Dep. Tr. at 304:1-15.

[132] Mr. Rafalski and Dr. Whitelaw criticize Mallinckrodt for removing a specific question regarding a customers' suspicious order monitoring program from the customer questionnaire in the course of the questionnaire development process. This particular question was included in later drafts of the questionnaire. MNK-T1_ 0008515547 (2012 questionnaire).

[133] Harper Dep. Tr. at 317:12-318:1; MNK-T1_0000477900; MNK-T1_0000263249.

[134] Rausch Dep. Tr. at 130:12-25 ("And what happened here, what occurred, was every year the sales force would get together for a week-long period of time to go over different things that were going on in sales and then something like this would be rolled out by Karen during that week -- Q. Okay. A. -- just to instruct them on what the new DEA regulations -- what the DEA regulations were, what we were doing as far as developing a new program, what their role was expected of them in this program, and so forth."); MNK-T1_0000296477; MNK-T1_0000296487.

[135] Harper Dep. Tr. at 292:12-17 ("the ultimate decision about whether an order was suspicious or not rests – always did rest with the controlled substances compliance group.").

pharmaceutical products and that he had discovered a bottle of Mallinckrodt product in the course of his investigation.[136] The Tennessee Police Officer requested that Mallinckrodt assist him in attempting to determine the source of the product.[137] Upon receipt of this request, Mallinckrodt immediately took action. Based on the lot number of the bottle, Mallinckrodt was able to research its shipping records and determine that only one distributor in Florida, Sunrise Wholesalers ("Sunrise") had received product from that lot at that point in time.[138] This, alone, of course, did not mean that product had been diverted from Sunrise, but Mallinckrodt took immediate steps to conduct due diligence on its customer.

107. The very next day, Mallinckrodt placed a hold on the Sunrise account, cutting off all further shipments of Mallinckrodt product to Sunrise.[139] Mallinckrodt's SOM Team then conducted an investigation into Sunrise, evaluating the information that Mallinckrodt had in its files while remaining in contact with the Tennessee Police Officer. Mallinckrodt's SOM Team learned that Sunrise employed a former DEA employee as a consultant who was responsible for ensuring that Sunrise sold to legitimate customers and took steps to ensure that Sunrise maintained effective controls against diversion. More importantly, Mallinckrodt learned that DEA had recently audited Sunrise and had offered no adverse findings.[140] Based on this information, Mallinckrodt's SOM Team made the decision to resume shipments to Sunrise, but also decided that it would conduct an onsite audit of this customer.[141]

108. Mallinckrodt's SOM Team promptly informed DEA of this information. Pete Kleissle, DEA St. Louis Diversion Investigator, informed Mallinckrodt that it "had acted in a responsible way and he saw no issues with regard to this matter."[142] Mr. Kleissle was very complimentary of Mallinckrodt's commitment to an open dialogue with DEA and provision of information to law enforcement.[143] With DEA's blessing, Mallinckrodt conducted an onsite audit of Sunrise in August of 2009. A team containing members of Mallinckrodt's compliance, sales, and data integrity groups reviewed Sunrise's building security, new customer screening process, suspicious order monitoring procedures, customer files, and DEA 222 forms. Mallinckrodt also spoke with Sunrise's onsite DEA consultant who was responsible for due diligence on Sunrise's customers.[144] I have reviewed both the processes and conclusions of Mallinckrodt's on-site audit of Sunrise and it is consistent with how I conducted due diligence audits of registrants in my 50 years of industry experience.[145] This proactive approach by Mallinckrodt demonstrates an

[136] MNK-T10000562325.
[137] *Id.*
[138] *Id.*
[139] MNK-T10000290242.
[140] MNK-T10000562325.
[141] *Id.*
[142] *Id.*
[143] *Id.*
[144] MNK-T10000296090; MNK-T1_0000307243.
[145] To the extent Plaintiffs' experts criticize Mallinckrodt's audit of Sunrise because it eventually surrendered its license to DEA, I find this hindsight criticism to be off base. My review indicates that Mallinckrodt conducted a thorough audit based on the information that was available to it. The fact that Sunrise surrendered its license nearly a

attempt to know its customers and engage in a partnership with law enforcement where evidence of diversion appears.

109. I understand that Mallinckrodt received positive feedback from DEA in 2009 and again in 2010, which illustrates that Mallinckrodt's program was in line with and exceeding DEA expectations and industry practice during this time. First, in a February 2009 meeting with Albany DEA, Diversion Investigator Heather White stated that she was "content and impressed" with Mallinckrodt's suspicious order monitoring and reporting mechanism.[146] The following year, a DEA St. Louis Diversion Program Manager stated that Mallinckrodt had the "best suspicious order monitoring process he has seen to date" and "what he expected from Mallinckrodt as an industry leader."[147] In my experience at DEA and as an industry consultant, positive feedback from DEA is meaningful and Mallinckrodt could rely on DEA's commentary as an indication of a sufficient suspicious order monitoring program.

110. Based on my experience at DEA and as an industry consultant, Mallinckrodt took the steps I would expect from a responsible registrant based on new DEA guidance lacking in specific direction. As I would expect, Mallinckrodt put together a cross-functional team to enhance the program in line with DEA's new guidance. At the same time, Mallinckrodt took actions that evidence good corporate citizenship when it learned of any potential issues with respect to one of its customers. Based on my experience, Mallinckrodt's anti-diversion program met the requirements of the regulation and statute, and went above and beyond industry standard for suspicious order monitoring during this time period.

111. It is my opinion that Mallinckrodt maintained sufficient and effective controls against diversion of controlled substances in the 2008-2009 time period.[148]

112. It is my opinion that Mallinckrodt's suspicious order monitoring system was sufficient and effective to detect and report suspicious orders to DEA in the 2008-2009 time period.

113. It is my opinion that Mallinckrodt appropriately utilized the information and data available to it in its controlled substances compliance program and its suspicious order monitoring program.

---

year later does not call into question the conclusions made by Mallinckrodt's team that were based on the facts available at the time.

[146] MNK-T1_0000275446.

[147] MNK-T1_0000421974.

[148] I have reviewed the Victor Borelli email that is referenced in Dr. Whitelaw's report. MNK-T1_0000559532. Based on my experience and my review of Mallinckrodt's suspicious order monitoring program, the email referring to opioids as Doritos was a callous and inappropriate email that was inconsistent with Mallinckrodt's role as a dedicated leader of suspicious order monitoring and DEA compliance. In my review of the documents, I have seen no evidence that anyone at the company was aware that this statement was made, and I have no doubt that if the company were aware of the statement that it would have taken appropriate action. I have also reviewed the email regarding Mr. Borelli from Cathy Stewart cited in Dr. Whitelaw's report, MNK-T1_0003028219, and after reviewing Ms. Stewart's testimony I understand that she was not concerned that Mr. Borelli was providing information that was inaccurate in an effort to make sales. Stewart Dep. Tr. at 65:20-23 ("Q. Do you recall anyone expressing any concern to you with respect to Mr. Borelli's communications with customers? A. No."); Stewart Dep. Tr. at 65:2-14.

114. It is my opinion that DEA guidance and industry standards evolved in the 2008-2009 time period and Mallinckrodt enhanced and upgraded its suspicious order monitoring and anti-diversion program to meet this changing DEA guidance and industry standards.

### C. 2010-2011: Incorporation of Chargeback Data

#### 1. 2010-2011 Regulatory Landscape

115. In the 2010-2011 time frame, there was no change to the CSA's anti-diversion requirements or suspicious order monitoring regulation.[149] Accordingly, consistent with prior years, neither the CSA nor the suspicious order monitoring regulation suggested that manufacturers needed to take any action to police the supply chain beyond the orders from their customers.

#### 2. 2010-2011 DEA Guidance

116. In the 2010-2011 time frame, DEA provided no further official guidance to industry. Manufacturers were still relying on the 2007 DEA Letter to understand DEA guidance. There was no DEA guidance requiring a registrant to know its customers' customers and no DEA guidance regarding an obligation or a suggestion that a registrant collect, maintain, and utilize downstream transactional data. Indeed, DEA witnesses have made clear that there was no such expectation and that they had not heard of such a requirement.[150]

117. The only time that Mallinckrodt heard the phrase "know your customers' customers" from DEA was in a one-off statement by a DEA Diversion Group Supervisor during a non-public audit where he told Mallinckrodt about a "'new direction' initiative whereby enforcement action will be aimed at all entities within the supply chain, including manufacturing registrants" because "[t]he expectation is becoming that suppliers have not only an obligation to know their customers but an additional responsibility to know their customers."[151] The Diversion Group Supervisor provided no further information on what know your customers' customers means or looks like, and provided no detail on what it means to implement this developing expectation in an anti-diversion program.

118. I am not aware of any other DEA field offices making a similar statement during this time period. In fact, I am aware of another DEA Diversion Investigator and Diversion Program

---

[149] Rannazzisi Dep. Tr. Vol. 1 at 253:10-23; Prevoznik Dep. Tr. Vol. 1 at 363:16-21 ("But since 1974, DEA has not promulgated any regulation providing further guidance to registrants on the supposed obligation to monitor and report suspicious orders, correct? A. Correct.").

[150] Prevoznik Dep. Tr. at 325:1-7 ("Q. But neither the statute nor the regulation says explicitly that manufacturers need to know their customers' customers, do they? A. It does not say that explicitly."); Ashley Dep. Tr. at 160:16-161:8 ("Q. As you sit here today, are you aware of any statute that requires a manufacturer to know its customer's customer? A. No, I am not aware of a statute that says that. Q. What about a regulation? A. No, I'm not aware of a regulation that says that.").

[151] MNK-T1_0008508032.

Manager stating that there was no such requirement.[152] Know your customers' customers was not something known to the industry prior to this point in time and the single mention by a DEA field office, later contradicted by another field office, does not appear to reflect a policy change. My understanding that there was no guidance from DEA that manufacturers should know their customers' customers is confirmed by DEA testimony in this case, which makes clear that there is no regulatory obligation, even to this day, for manufacturers to know their customers' customers.[153]

119. Based on my review of the documents and my expertise in the industry, there was no shift in DEA guidance in the 2010-2011 time period that would have created new obligations, including any obligation or expectation that manufacturers should monitor their customers' customers.

### 3. 2010-2011 Industry Standards

120. During this time**,** the industry standard was to monitor orders from your own direct customers. I am not aware of other manufacturers during this time period that monitored the downstream registrants that purchased the manufacturer's product from distributors. It was not standard industry practice for manufacturers to collect, maintain, or utilize any downstream transactional data for anti-diversion purposes because DEA had never mentioned the possibility of using downstream transactional data for these purposes.

121. Chargeback data is financial reconciliation data; it does not show "orders" placed to a manufacturer. Chargebacks are credits provided to distributors on certain sales for which the distributor's sale price is less than the amount they paid the manufacturer for the product.[154] When submitting chargeback requests to manufacturers, distributors must provide manufacturers with information indicating how much product was sold and to whom.

122. I have come to understand that there are significant limitations regarding chargeback data that make it ill-suited for use in a suspicious order monitoring program.[155]

a. By the time manufacturers receive chargeback data from the distributor about a distributor-to-dispenser sale, that sale has already taken place. There is no opportunity for the manufacturer to "halt" or otherwise impact the transaction.

---

[152] MNK-T1_0000270020 (Eileen Spaulding emails Karen Harper about a conversation with DI Heather White, who stated that she called NYC and no one there including Diversion Program Manager Sue Baker has heard anything about "know your customers' customer" and that the regulations do not reflect such a requirement.); Harper Dep. Tr. at 144:8-17 ("DEA Albany contradicted that statement" by the DEA St. Louis Field Office regarding knowing your customers' customers.).

[153] Prevoznik Dep. Tr. Vol. 1 at 325:1-7; Ashley Dep. Tr. at 160:16-161:8 ("Q. As you sit here today, are you aware of any statute that requires a manufacturer to know its customer's customer? A. No, I am not aware of a statute that says that. Q. What about a regulation? A. No, I'm not aware of a regulation that says that.").

[154] Buthusiem Rep. at 3-6.

[155] *Id.*

b. Manufacturers do not get chargeback data when they sell directly to the distribution centers of retail pharmacy chains.

c. The data includes only that manufacturer's. Therefore, the data provides no context – e.g., it does not show what other opioids or non-opioid products manufactured by others the pharmacy is purchasing.

d. The data only contains information about product the distributor shipped to the dispenser. It contains no information about how, by whom, or to whom the product is prescribed.

123. Similarly, based on my experience in the industry, it was not standard practice for manufacturers to utilize prescription data for anti-diversion efforts. Prescription data does not show "orders" and DEA never suggested to industry that this data should be collected by manufacturers, analyzed as if they were orders, or utilized for anti-diversion purposes generally.

124. Based on my experience within DEA and as a compliance consultant for industry, there was no industry standard of monitoring downstream transaction or purchases and no expectation that that would be part of an anti-diversion and/or suspicious order monitoring program during this time.

#### 4. 2010-2011 Mallinckrodt Program

125. In 2010 and 2011, Mallinckrodt continued to enhance its suspicious order monitoring program. At the same time, Mallinckrodt worked to create leading anti-diversion practices that allowed it to not only find out information about its customers but also find out information about downstream registrants that purchased Mallinckrodt product from Mallinckrodt's customers. I have reviewed Mallinckrodt's continuing enhancements and efforts to expand its anti-diversion program and evaluated that program and its efforts with respect to monitoring transactional data.

126. As previously discussed, in 2009, in connection with the Sunrise audit, Mallinckrodt's Controlled Substances Compliance group became aware that its finance department possessed chargeback data to reconcile some downstream transactions.[156] Mallinckrodt began to explore and evaluate the potential of using this financial data in its anti-diversion efforts. In 2010, Mallinckrodt began to see public news reports of diversion in Florida and its finance team undertook an analysis of this downstream data. Mallinckrodt discovered that its chargeback data could be used to help it better know its customers. [157] While not all customers submit chargeback data on all downstream transactions, the transactions that were visible in the chargeback data showed the name and DEA number of the downstream entity, the type of product sold, the volume of product sold, the date

[156] Harper Dep. Tr. at 353:9-20.
[157] Harper Dep. Tr. at 360:2-16.

of the sale.[158] By understanding where its customers were selling Mallinckrodt product, Mallinckrodt was better equipped to scrutinize its customers' business practices.

127. Based on what it learned from the chargeback data about customers' sales into the state of Florida, Mallinckrodt then took proactive steps with respect to three particular customers – Keysource, Masters, and Cedardale[159] – that were shipping Mallinckrodt product to Florida. First, Mallinckrodt requested that the customers cease shipping oxycodone 15 mg and 30 mg dosage units to certain pharmacies and demanded an explanation for these sales.[160] Then, Mallinckrodt conducted formal audits of all three customers.[161] Finally, Mallinckrodt informed DEA about the steps it was taking with respect to each customer.[162] Based on my experience, Mallinckrodt's customer audits went above and beyond common practices for manufacturers at the time, and set the industry standard for manufacturer audits of distributors.

128. Despite conflicting suggestions from the DEA St. Louis Field Office and the DEA Albany Field Office about manufacturers knowing their customers' customers (see paragraphs 118-119) and no further guidance from DEA about what this meant or how to implement it, Mallinckrodt forged ahead to attempt to integrate chargeback data into its anti-diversion program to better understand where its products were being distributed.[163] The Controlled Substances Compliance group worked closely with the finance department to run chargeback data reports, understand what the data showed and what to look for in the voluminous data, and evaluate whether and how the data could be incorporated in the anti-diversion program.

129. Based on my review of documents and testimony, Mallinckrodt developed a chargeback monitoring program that went above and beyond DEA expectations. The program periodically reviewed chargeback data to look for high volume pharmacies or pharmacies whose transactional patterns raised questions. The program also reviewed certain other media and publically available information to identify downstream registrants that may pose a risk of diversion. Mallinckrodt shared its new chargeback monitoring initiative with the DEA St. Louis Field Office in 2010 and received feedback from the Diversion Program Manager that "the information Mallinckrodt presented was the best Suspicious Order Monitoring process he has seen to date and what he expected from Mallinckrodt as an industry leader."[164]

---

[158] Buthusiem Rep. at 3-6.
To the extent Dr. Whitelaw claims that Mallinckrodt was ignoring diversion in Ohio, that is incorrect. MNK audited two distributors located in Ohio and reported findings to DEA.
[160] MNK-T1_0000564558; MNK-T1_0000558232.
[161] MNK-T1_0000466855; MNK-T1_0000283323; MNK-T1_0004251843.
[162] MNK-T1_0000558215; Spaulding Dep. Tr. at 198:22-201:5 (testifying regarding a November 2010 meeting with DEA).
[163] MNK-T1_0000270090 (10/31/2010 Harper email "In essence, the program was expanded within the last month to our customers' customers"); Gillies 30(b)(6) Dep. Tr. at 89:6-11 ("Q. And so at least as of July 2010, Mallinckrodt -- is it fair to say that Mallinckrodt began contemplating use of chargeback data in connection with its suspicious order monitoring program? A. Yes."); Harper Dep. Tr. at 374:10-24, 375:16-376:3.
[164] MNK-T1_0000421974.

130. As part of this chargeback monitoring program, Mallinckrodt developed the "chargeback restriction," a mechanism to disincentivize Mallinckrodt's customers from selling Mallinckrodt product to downstream pharmacies that may pose a risk of diversion.[165] If Mallinckrodt decided to restrict chargebacks to a pharmacy, it would send a letter to distributors and to DEA, informing the distributors that it would not pay chargebacks to distributors who sold its product to the restricted pharmacy, in an effort to raise awareness of that pharmacy and spur further action by the distributors and perhaps DEA. Mallinckrodt did not have enough information to determine whether diversion was taking place, but used the chargeback restriction mechanism to identify the pharmacies for distributors and DEA based on its limited view through the chargeback data. In 2011, Mallinckrodt chargeback restricted more than thirty pharmacies in Florida and more than twenty pharmacies in other states.[166]

131. In spring 2011, Mallinckrodt sought a meeting with DEA headquarters to share the work that it was doing on chargeback review and monitoring and its audits of distributors. On August 23, 2011, Mallinckrodt representatives from compliance, legal, and security met with DEA Office of Diversion Control and Quota section in Washington, DC.[167] After Mallinckrodt presented its anti-diversion program, DEA asked Mallinckrodt to focus its anti-diversion efforts on its largest distributors and do more to address oxycodone diversion in Florida. [168]

132. After the meeting with DEA, Mallinckrodt took action immediately, both with respect to its own customers and with respect to downstream registrants. Mallinckrodt put together a plan to: (1) promptly suspend sales of Mallinckrodt oxycodone 15 mg and 30 mg tablets to distributors located in Florida; (2) set up in-person meetings with the larger distributors; (3) use chargeback data to identify the pharmacies purchasing the largest amounts of Mallinckrodt oxycodone 15 mg and 30 mg tablets inside and outside of Florida from Mallinckrodt's four largest distributor customers; (4) meet with those distributors and ask them to share their due diligence on each of those pharmacies; (5) conduct site-visits to certain Florida and Nevada pharmacies on that list to evaluate distributors' customer due diligence files on those pharmacies; and (6) chargeback restrict those pharmacies that Mallinckrodt believed, after its investigation and review of distributors' customer due diligence files, represented an unacceptable risk of diversion.[169]

133. Based on my review of the documents and testimony, Mallinckrodt followed through on these plans. Mallinckrodt suspended shipments as planned, met with its four largest

[165] Ratliff Dep. Tr. at 345:13-346:10 ("A. What we would do, we would recommend to our -- the distributor, it was our distributor, one of our customers, we could say, We are going to deny chargebacks, and so that distributor normally would then deny product to that particular end user, which would be a pharmacy."); Spaulding Dep. Tr. at 216:5-217:20.
[166] MNK-T1_0000289385; MNK-T1_0007711299; MNK-T1_0001364741.
[167] MNK-T1_0007726908.
[168] MNK-T1_0007726908.
[169] MNK-T1_0008507518; MNK-T1_0007726908; Ratliff Dep. Tr. at 59:10-21; MNK-T1_0001364741 (In November 2011, Mallinckrodt sent chargeback restriction letters to 45 distributors to restrict chargeback for 17 pharmacies).

distributors, reviewed distributors' customer due diligence files on pharmacies purchasing large amounts of Mallinckrodt oxycodone 15 mg and 30 mg tablets from the distributor, conducted its own pharmacy site visits, and chargeback restricted certain pharmacies. Mallinckrodt's security director at the time, Bill Ratliff, testified that "the very next week I was in Florida… two of our forensic auditors to cover the east side of the state, because they had Spanish speaking ability, and I covered the west side of the state."[170] By early October 2011, Ratliff and his team had visited at least twenty pharmacies in Florida and Nevada.[171] In September 2011 and again in November 2011, Mallinckrodt restricted chargebacks to distributors in connection with sales to certain pharmacies in and outside of Florida and shared those restriction letters with DEA.[172] Throughout the fall of 2011 and into the first quarter of 2012, Mallinckrodt remained in regular communication with DEA and provided updates on its actions and initiatives.[173]

134. I understand that in late 2010, Mallinckrodt retained Howard Davis as a consultant to assist the company in continuing to enhance and improve Mallinckrodt's suspicious order monitoring program.[174] It is my opinion that Mr. Davis's analysis and recommendations to Mallinckrodt[175] made incorrect conclusions about Mallinckrodt's program, applied incorrect standards, and made incorrect recommendations for Mallinckrodt that were not consistent with DEA guidance to manufacturers or with industry standards at the time. For example, Mr. Davis copied and pasted a number of recommendations included in DEA guidance letters from 2006 and 2007 that related solely to distributors' pharmacy customers. For instance, Mr. Davis recommended that Mallinckrodt ask its distributor customers questions that were clearly meant for pharmacies, such as whether insurance plans are accepted and whether their customers are soliciting purchasers via the internet.[176] Mr. Davis further suggested that Mallinckrodt ask its customers whether they self-medicated or were prescribing to family members.[177] These recommendations demonstrate that Mr. Davis appears to have had no understanding of Mallinckrodt's business and was unable to comprehend the various entities that make up the controlled substances supply chain. In short, given Mr. Davis's lack of knowledge and understanding of the very manufacturing business upon which he was expected to consult, I conclude that any guidance he provided to Mallinckrodt was severely flawed and he did not add value as a consultant to the company.

---

[170] Ratliff Dep. Tr. at 59:10-21 ("A. We took the top three, McKesson, Cardinal, and AmerisourceBergen, and we looked at their top ten pharmacies in Florida. So that was -- there was -- were a total of 30 pharmacies. They were the ones that purchased the most of the oxycodone 30s through their distributors. And so when we identified those -- and as I said, when DEA told us that, the very next -- next week I was in Florida. And I had -- I caused two of our forensic auditors to cover the east side of the state, because they had Spanish speaking ability, and I covered the west side of the state."); Harper Dep. Tr. at 400:16-401:4.

[171] MNK-T1_0008561121; MNK-T1_0008561129; MNK-T1_0008561151; MNK-T1_0000391982; MNK-T1_0008561125; MNK-T1_0008500998; MNK-T1_0008560029; MNK-T1_0004822078; MNK-T1_0000311568.

[172] MNK-T1_0000289384; MNK-T1_0001364741.

[173] MNK-T1_0008507518.

[174] MNK-T1_0000477912.

[175] MNK-T1_0000269399.

[176] MNK-T10000269399.

[177] MNK-T10000269401.

135. It is my opinion that Mallinckrodt maintained sufficient and effective controls against diversion of controlled substances in the 2010-2011 time period.

136. It is my opinion that Mallinckrodt's suspicious order monitoring system was sufficient and effective to detect and report suspicious orders to DEA in the 2010-2011 time period.

137. It is my opinion that in the 2010-2011 time period Mallinckrodt appropriately utilized the information and data available to it in its controlled substances compliance program and its suspicious order monitoring program.

138. It is my opinion that DEA guidance and industry standards evolved in the 2010-2011 time period and Mallinckrodt enhanced and upgraded its suspicious order monitoring and anti-diversion program to meet this changing DEA guidance and industry standards.

### D. 2012 to 2018: Continuing Evolution and Enhancement

#### 1. 2012-2018 Regulatory Landscape

139. From 2012 to the present, there has been no change to the CSA's anti-diversion requirements or suspicious order monitoring regulation.[178] Accordingly, consistent with prior years, neither the CSA nor the suspicious order monitoring regulation suggested that manufacturers needed to take any action to police the supply chain beyond the orders from their customers.

#### 2. 2012-2018 DEA Guidance

140. In the post-2012 time period, there has also been no further official guidance from DEA concerning anti-diversion and suspicious order monitoring obligations. In June 2012, DEA published a guidance letter reiterating the same information as the December 2007 letter.[179] The June 2012 DEA Letter does not mention or suggest to manufacturers that they should know their customers' customers, and does not mention or suggest any obligation to collect, maintain, and utilize downstream transactional data as part of their anti-diversion or suspicious order monitoring programs. Essentially, the state of official DEA guidance remains unchanged since 2007.[180]

#### 3. 2012-2018 Industry Standards

141. Because DEA offered no further guidance, industry standards remained largely the same in the 2012-2018 time period. Based on my experience within DEA and as a compliance consultant for industry, there was no industry standard at this time for manufacturers to

[178] Rannazzisi Dep. Tr. Vol. 1 at 253:10-23; Prevoznik Dep. Tr. Vol. 1 at 363:16-21 ("But since 1974, DEA has not promulgated any regulation providing further guidance to registrants on the supposed obligation to monitor and report suspicious orders, correct? A. Correct.").

[179] ABDCMDL00269683.

[180] Mr. Rafalski heavily relies on the *Masters Pharmaceuticals* decision in creating additional suspicious order monitoring obligations for registrants that are not stated in any regulations or DEA guidance. The *Masters* decision is not relevant to my opinions because it came out in 2017 and does not apply retroactively, and Mallinckrodt's program was consistent with the *Masters* decision.

monitor downstream registrants that purchased their product from distributors, and no expectation that such activity would be part of a compliance or suspicious order monitoring program during this time. In addition, it was not standard industry practice for manufacturers to collect, maintain, or utilize any downstream transactional data for anti-diversion purposes because DEA had never mentioned the possibility of using downstream transactional data for these purposes.

#### 4. 2012-2018 Mallinckrodt Program[181]

142. In 2012, Mallinckrodt further enhanced its anti-diversion and suspicious order monitoring efforts. First, Mallinckrodt revised its suspicious order monitoring algorithm to generate reports twice each business day, flagging orders based on number of orders per month and volume of orders per month.[182] In September 2012, "Do Not Ship" controls were made automatic instead of manual so that an order could not be shipped while investigation was ongoing.[183] In November 2012, the algorithm changed from [redacted], increasing the number of flagged orders, all of which Mallinckrodt conducted due diligence on prior to shipment.[184] Mallinckrodt reported all flagged orders to DEA, sending reports twice each business day.[185] Mallinckrodt has made continued revisions and improvements to its suspicious order monitoring process and procedures since 2012, the most recent in 2018.[186]

143. In 2012, Mallinckrodt also expanded its customer audits, including audits of larger distributors.[187]

144. Mallinckrodt also continued to restrict chargebacks to distributors in connection with sales by distributors to pharmacies nationwide that may be indicative of diversion.[188] Each year from 2012 to the present, the company periodically identified pharmacies across the country to chargeback-restrict.[189] Mallinckrodt formalized the chargeback restriction process and developed pharmacy information sheets to standardize the pharmacy investigation process.[190] As discussed above, whenever Mallinckrodt put a pharmacy on its chargeback restriction list, it provided notice to all of Mallinckrodt's distributor customers as well as DEA.

---

[181] I understand that neither Mr. Rafalski nor Dr. Whitelaw offer an opinion on Mallinckrodt's anti-diversion program after 2012 and no Plaintiffs' experts claim that Mallinckrodt's anti-diversion program did not meet DEA requirements and expectations after 2012.
[182] MNK-T1_0002357607.
[183] MNK-T1_0002357607.
[184] MNK-T1_0005620500.
[185] *E.g.*, MNK-T1_0008509735; MNK-T1_0002255019; MNK-T1_0008436462.
[186] MNK-T1_0007476261 (October 2012 policy); MNK-T1_0005620500 (November 2012 policy); MNK-T1_0000511246 (2015 policy); MNK-T1_0004155833 (2018 policy).
[187] MNK-T1_0008435608; MNKT1_0007727911.
[188] MNK-T1_0001384980.
[189] MNK-T1_0008502183; MNK-T1_0007727449; MNK-T1_0007705938.
[190] MNK-T1_0004155830; MNK-T1_0004155827.

145. As an example of the chargeback restriction process, in October 2015, European Apothecary pharmacy came to Mallinckrodt's attention via media reports. Jennifer Buist of the Controlled Substances Compliance group consulted chargeback data and then sent distributors AmerisourceBergen, Bellco, and HD Smith a pharmacy information sheet requesting due diligence on European Apothecary.[191] Bellco shortly thereafter returned the pharmacy information sheet, indicating that European Apothecary had been recently restricted internally due to similar media reports.[192] Immediately after receiving the pharmacy information sheet from Bellco, Buist recorded this information about European Apothecary and contacted the appropriate colleagues to implement a chargeback restriction. Mallinckrodt sent a chargeback restriction letter concerning European Apothecary to all distributors.[193] Mallinckrodt reported the chargeback restriction to DEA as well.[194]

146. It is my opinion that Mallinckrodt maintained sufficient and effective controls against diversion of controlled substances 2012 to 2018.

147. It is my opinion that Mallinckrodt's suspicious order monitoring system was sufficient and effective to detect and report suspicious orders to DEA from 2012 to 2018.

148. It is my opinion that Mallinckrodt appropriately utilized the information and data available to it in its controlled substances compliance program and its suspicious order monitoring program from 2012 to 2018.

## VIII. Mallinckrodt's 2017 Settlement Does Not Establish Or Recognize Any "Know Your Customers' Customers" Requirement And Does Not Change Opinion Regarding Mallinckrodt's Compliance With The CSA

149. Based on my review of documents and deposition testimony in this case and Mallinckrodt's Memorandum of Agreement with DEA, Mallinckrodt made a limited admission in 2017 that at certain times prior to January 1, 2012, its program did not meet the standards outlined in the DEA guidance letters.[195] Mallinckrodt does not admit that it has any obligation to know its customers' customers or monitor downstream transactional data.[196] In the MOA, Mallinckrodt agreed to two different tasks: suspicious order reporting, required by DEA regulation, and chargeback monitoring, not required by DEA regulation.[197]

150. In my experience with DEA and in industry, it is common for an entity to agree to a Memorandum of Agreement in order to avoid the burden of litigation and resolve a disagreement with the agency.

---

[191] MNK-T1_0002265146; MNK-T1_0001810925.
[192] MNK-T1_0002265149.
[193] MNK-T1_0007727449; MNK-T1_0007727447.
[194] MNK-T1_0002261388.
[195] MNK-T1_0000557100.
[196] MNK-T1_0000557100.
[197] MNK-T1_0000557100.

151. In my experience with DEA and in industry, it is possible for an entity to agree in a Memorandum of Agreement to do more than the relevant statute and regulations require. Furthermore, a Memorandum of Agreement is not binding on third parties and does not have the force of law.

152. In my opinion, Mallinckrodt's limited admission in the 2017 settlement with DEA does not change my opinion that Mallinckrodt's anti-diversion program was consistent with anti-diversion regulations, guidance, and industry standards throughout the Review Period.

## IX. McCann and Keller Methodologies for Flagging Transactions

153. I have also reviewed the Report and Supplemental Reports of Plaintiffs' experts Dr. Craig McCann and Lacy Keller. Dr. McCann and Ms. Keller claim to utilize five methodologies for identifying orders that could have been flagged within DEA's ARCOS data and Defendants' transaction data. Dr. McCann terms these methods as: "Maximum Monthly, Trailing 6 Month Threshold," "2x Trailing 12 Month average," "Extraordinary Order Method – 3x Trailing 12 Month Average," "Maximum 8,000 Dosage Units Monthly," and "Maximum Daily Dosage Units."[198] These methodologies are pulled from Mr. Rafalski's expert report and no reason is given as to why any of these methodologies would be appropriate for any particular Defendant.[199]

154. Neither Dr. McCann nor Ms. Keller offer any opinion as to whether any of the "flagged" transactions are, in fact, suspicious under the DEA' suspicious order monitoring regulation. However, Mr. Rafalski, without any analysis, simply adopts the analyses of both Dr. McCann and Ms. Keller and contends that each of the flagged orders is, in fact, suspicious.[200] Each of these reports rests on assumptions that are fundamentally flawed. Notably, as both DEA and industry understood, suspicious order monitoring is not one-size-fits all. Each and every registrant has a different business model and different customer base. Therefore, attempting to apply simplistic formulas across numerous registrants without conducting an actual evaluation of each registrant's business model and customer base does not provide an accurate way to evaluate that registrant's orders. In fact, the flaws in this approach are highlighted by the fact that Dr. McCann and Ms. Keller apply the exact same formulas to both distributor and manufacturer registrants. As discussed earlier in this report, these different registrant classes have very different business models and customer bases. A manufacturer may sell to a few dozen distributors while a distributor may sell to tens of thousands of retail pharmacies. Dr. McCann and Ms. Keller simply ignore these essential differences. Throughout my experience, I understood that each registrant needed to be evaluated individually, and one could not apply a single suspicious order monitoring program to different registrants, and certainly not to difference classes of registrants. The regulatory guidance provided by DEA makes this fact clear as DEA expected each registrant to create its own system to determine when orders were actually suspicious.[201] As such, the methodologies utilized

[198] McCann Rep. at 56-72; Keller Rep. at 16-22.
[199] Rafalski Rep. at 41.
[200] Rafalski Rep. at 40-41.
[201] US-DEA-00001767; US-DEA-00005941.

by Dr. McCann and Ms. Keller are merely a subset of the various ways by which a registrant could analyze orders for further diligence as part of its suspicious order monitoring program.

155. More importantly, Dr. McCann and Ms. Keller both base their reports on a flawed premise – that the registrants did not effectively investigate the flagged transactions. This assumption is based solely on the instruction of Plaintiffs' counsel as neither Dr. McCann nor Ms. Keller conducted any review of any Defendants' due diligence files.[202] As such, neither Dr. McCann nor Ms. Keller has any idea whether the orders flagged by the methodologies were in fact investigated by the registrants.

156. Furthermore, both Dr. McCann and Ms. Keller take this flawed assumption to an extreme and untenable position. As soon as one order is flagged, Dr. McCann and Ms. Keller assume that all subsequent orders should be flagged and again that no due diligence was conducted. I have never heard of such an approach to suspicious order monitoring. The CSA, DEA regulations, DEA guidance, and industry standards have never instructed or required manufacturers and distributors to stop selling controlled substances to a customer if one of that customer's orders is flagged by its suspicious order monitoring algorithm. In addition, this position appears to utilize a "suspicious customer" approach, whereas the applicable DEA regulation clearly is focused on monitoring and reporting individual orders. These flawed assumptions cause Dr. McCann and Ms. Keller to immensely overstate the number of orders flagged by each of their flawed methods. In short, the analyses done by Dr. McCann and Ms. Keller have no basis and are simply created based on faulty assumptions by Plaintiffs. I do not believe that they provide any useful information in evaluating the Defendants' suspicious order monitoring programs.

157. It is my opinion that a suspicious order monitoring system that meets the regulations and expectations of DEA must be tailored to each individual registrant's business and the one-size-fits-all approach that Plaintiffs' counsel asked Dr. McCann and Ms. Keller to apply in their expert reports in this case is incorrect, is contrary to DEA guidance, and does not provide any useful information relating to suspicious orders for each of the Defendants.

[202] Keller Rep. at 14; McCann Rep. at 20.

Dated: May 31, 2019

Ronald W. Buzzeo, R.Ph.